7.01.47	Bariatric Surgery		
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Policy Statement

Bariatric Surgery in Adults With Class 3 Obesity (BMI greater than or equal to 40 kg/m^2)

I. The following bariatric surgery procedures may be considered **medically necessary** for the treatment of class 3 obesity (BMI greater than or equal to 40.0 kg/m^2) in adults (ages 18 and older) who have failed weight loss by conservative measures:
   A. Open or laparoscopic gastric bypass using a Roux-en-Y
   B. Laparoscopic adjustable gastric banding
   C. Open or laparoscopic sleeve gastrectomy (SG)
   D. Open or laparoscopic biliopancreatic bypass/diversion (i.e., Scopinaro procedure) with duodenal switch (DS)

Bariatric Surgery in Adults With Class 2 Obesity (BMI greater than or equal to 35 to 39.9 kg/m^2)

II. The following bariatric surgery procedures may be considered **medically necessary** for the treatment of class 2 obesity in individuals with at least 1 obesity-related comorbid condition who have failed weight loss by conservative measures:
   A. Open or laparoscopic gastric bypass using a Roux-en-Y
   B. Laparoscopic adjustable gastric banding
   C. Open or laparoscopic sleeve gastrectomy (SG)
   D. Open or laparoscopic biliopancreatic bypass/diversion (i.e., Scopinaro procedure) with duodenal switch (DS)

Bariatric surgery should be performed in appropriately selected individuals, by surgeons who are adequately trained and experienced in the specific techniques used, and in institutions that support a comprehensive bariatric surgery program, including long-term monitoring and follow-up postsurgery.

Bariatric Surgery in Individuals With Class 1 Obesity (BMI greater than or equal to 30 to 34.9 kg/m^2) and Type 2 Diabetes

III. For individuals with Class 1 obesity (BMI greater than or equal to 30 to 34.9 kg/m^2) and type 2 diabetes, the following bariatric surgery procedures may be considered **medically necessary** in adults who have failed weight loss by conservative measures:
   A. Open or laparoscopic gastric bypass using a Roux-en-Y
   B. Laparoscopic adjustable gastric banding
   C. Open or laparoscopic sleeve gastrectomy (SG)
   D. Open or laparoscopic biliopancreatic bypass/diversion (i.e., Scopinaro procedure) with duodenal switch (DS)

IV. Bariatric surgery is considered **investigational** for individuals with Class 1 obesity who do not have type 2 diabetes.

V. Bariatric surgery is considered **investigational** for individuals with a BMI less than 30 kg/m^2.

VI. The following bariatric surgery procedures are considered **investigational** for the treatment of obesity:
   A. Vertical-banded gastroplasty
   B. Gastric bypass using a Billroth II type of (mini-gastric bypass)
   C. Biliopancreatic diversion (BPD) without DS
   D. Long-limb gastric bypass procedure (i.e., greater than 150 cm)

E. Two-stage bariatric surgery procedures (e.g., SG as initial procedure followed by BPD at a later time)
F. Laparoscopic gastric plication
G. Single anastomosis duodeno-ileal bypass with SG

Revision Bariatric Surgery

VII. Revision surgery to address perioperative or late complications of a bariatric procedure may be considered **medically necessary**. These include but are not limited to:
A. Staple line failure
B. Obstruction
C. Stricture
D. Nonabsorption resulting in hypoglycemia or malnutrition
E. Weight loss of 20% or more below ideal body weight
F. Band slippage that cannot be corrected with manipulation or adjustment (see policy guidelines section)

VIII. Revision of a primary bariatric procedure that has failed due to dilation of the gastric pouch or dilation proximal to an adjustable gastric band (documented by upper gastrointestinal examination or endoscopy) may be considered **medically necessary** if the initial procedure was successful in inducing weight loss prior to pouch dilation, and the individual has been compliant with a prescribed nutrition and exercise program.

IX. Revision surgery to address severe gastroesophageal reflux disease refractory to medical treatment may be considered **medically necessary**.

Bariatric Surgery in Adolescents

X. Bariatric surgery in adolescents may be considered **medically necessary** according to similar weight-based criteria used for adults, but greater consideration should be given to psychosocial and informed consent issues. In addition, any devices used for bariatric surgery must be used in accordance with the U.S. Food and Drug Administration approved indications.

Bariatric Surgery in Preadolescent Children

XI. Bariatric surgery is considered **investigational** for the treatment of obesity in preadolescent children.

Concomitant Hiatal Hernia Repair With Bariatric Surgery

XII. Repair of a hiatal hernia at the time of bariatric surgery may be considered **medically necessary** for individuals who have a preoperatively diagnosed hiatal hernia with indications for surgical repair.

XIII. Repair of a hiatal hernia that is diagnosed at the time of bariatric surgery, or repair of a preoperatively diagnosed hiatal hernia in individuals who do not have indications for surgical repair is considered **investigational**.

Endoscopic Procedures

XIV. The following endoscopic procedures are **investigational** as a primary bariatric procedure or as a revision procedure (i.e., to treat weight gain after bariatric surgery to remedy large gastric stoma or large gastric pouches):
A. Insertion of the StomaphyX™ device,
B. Endoscopic gastroplasty,
C. Use of an endoscopically placed duodenojejunal sleeve,
D. Intragastric balloons, and
E. Aspiration therapy device.

Esophagogastroduodenoscopy with Bariatric Surgery

I. The routine use of esophagogastroduodenoscopy with bariatric surgery is considered investigational.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Weight-Related Complications

Clinical Practice Guidelines list the following conditions weight-related complications, defined as conditions caused by or exacerbated by excess adiposity:[1,]

- Asthma
- Cardiovascular disease
- Certain types of cancer (e.g., colorectal cancer)
- Type 2 diabetes
- Dyslipidemia
- Gastroesophageal reflux disease (GERD)
- Hypertension
- Infertility
- Male hypogonadism
- Mental health (depression)
- Metabolic syndrome
- Nonalcoholic fatty liver disease (nonalcoholic fatty liver and nonalcoholic steatohepatitis)
- Obstructive sleep apnea
- Osteoarthritis
- Polycystic ovarian syndrome
- Prediabetes
- Stroke
- Urinary stress incontinence

Recommendations specify that bariatric surgery may be considered in individuals with a body mass index (BMI) of greater than or equal to 35 kg/m^2 and 1 or more severe obesity-related complications, including type 2 diabetes, hypertension, obstructive sleep apnea, obesity-hypoventilation syndrome, Pickwickian syndrome, nonalcoholic fatty liver disease or nonalcoholic steatohepatitis, pseudotumor cerebri, GERD, asthma, venous stasis disease, severe urinary incontinence, debilitating arthritis, or considerably impaired quality of life.[1,]Guidelines do not explicitly define thresholds for determining the clinical significance of obesity-related conditions that would qualify individuals for bariatric surgery, however.

Bariatric Surgery Selection Criteria

Patients should have documented failure to respond to conservative measures for weight reduction prior to consideration of bariatric surgery, and these attempts should be reviewed by the practitioner prior to seeking approval for the surgical procedure. As a result, some centers require active participation in a formal weight reduction program that includes frequent documentation of weight, dietary regimen, and exercise. However, there is a lack of evidence on the optimal timing, intensity, and duration of nonsurgical attempts at weight loss, and whether a medical weight loss program immediately preceding surgery improves outcomes.

Patients with a BMI of 50 kg/m^2 or more need a bariatric procedure to achieve greater weight loss. Thus, the use of adjustable gastric banding, which results in less weight loss, should be most useful as a procedure for patients with a BMI less than 50 kg/m^2. Malabsorptive procedures, although they produce more dramatic weight loss, potentially result in nutritional complications, and the risks and

benefits of these procedures must be carefully weighed in light of the treatment goals for each patient. Patients who undergo adjustable gastric banding and fail to achieve adequate weight loss must show evidence of postoperative compliance with diet and regular bariatric visits prior to consideration of a second bariatric procedure.

Recommendations specify that BMI thresholds for defining obesity do not apply uniformly across all populations. Clinical obesity in the Asian population is identified in individuals with a BMI greater than or equal to 25 kg/m^2.

Considerations for Bariatric Surgery in Adolescents

Guidelines for bariatric surgery in adolescents are not uniform, with variability in weight-based criteria, ranging from a BMI of 35 kg/m^2 with comorbidities to a BMI of 50 kg/m^2. Most guidelines use weight-based criteria that parallel those for adults.

In addition to the weight-based criteria, there is greater emphasis on issues of developmental maturity, psychosocial status, and informed consent for adolescent patients. All guidelines mention these issues, but recommendations are not uniform The following are examples from U.S. guidelines published since 2013 that address issues of maturity and psychosocial status.

Endocrine Society

- The child has attained Tanner 4 or 5 pubertal development and final or near-final adult height.
- Psychological evaluation confirms the stability and competence of the family unit.
- The patient demonstrates the ability to adhere to the principles of healthy dietary and activity habits (Styne et al, 2017).

Bariatric Procedure Selection for Adolescents

The choice of procedure in adolescents may also differ from adults, but there is a lack of consensus in guidelines or expert opinion as to the preferred procedure(s) for adolescents. The following factors should be considered in the choice of bariatric surgery in adolescents (Aikenhead et al, 2011; PMID: 25586970):

- As in adults, laparoscopic gastric bypass is the most common procedure in adolescents.
- Devices used for laparoscopic adjustable gastric band (LAGB) do not have FDA approval in the United States for individuals younger than age 18 years.
- Some guidelines for bariatric surgery in adolescents do not recommend biliopancreatic diversions (BPD) because of the greater frequency of nutritional deficiencies on long-term follow-up, but other guidelines do not specify that BPD not be done in adolescents.

In 2018, the American Society for Metabolic and Bariatric Surgery (ASMBS) published an updated guideline on pediatric metabolic and bariatric surgery (Pratt et al, 2018). With regard to choice of procedure, the guideline stated:

- "Vertical sleeve gastrectomy has become the most used and most recommended operation in adolescents with severe obesity for several reasons, near-equivalent weight loss to RYGB [Roux-en-Y gastric bypass] in adolescents, fewer reoperations, better iron absorption, and near-equivalent effect on comorbidities as RYGB in adolescents. However, given the more extensive long-term data available for RYGB, we can recommend the use of either RYGB or VSG in adolescents."

Hiatal Hernia Repair Guidelines

In 2018, the ASMBS and the American Hernia Society published a consensus guideline on bariatric surgery and hernia surgery (Menzo et al, 2018). The guideline contained the following conclusions and summary recommendations:

- "There is a significant link between obesity and hernia formation both after abdominal surgery and de novo. There is also evidence that abdominal wall hernia can more commonly present with obstruction or strangulation in patients with obesity."
- "There is a higher risk for complications and recurrence after hernia repair in patients with obesity."
- "In patients with severe obesity and ventral hernia, and both being amenable to laparoscopic repair, combined hernia repair and metabolic/bariatric surgery may be safe and associated with good short-term outcomes and low risk of infection. There is a relative lack of evidence, however, about the use of synthetic mesh in this setting."
- "In patients with severe obesity and abdominal wall hernia that is not amenable to laparoscopic repair, a staged approach is recommended. Weight loss prior to hernia repair is likely to improve hernia repair outcomes. Metabolic/bariatric surgery appears to provide far more significant and rapid weight loss than other modalities and would be a good option for selected patients with severe obesity and large, symptomatic abdominal wall hernia."

The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) issued evidence-based guidelines for the management of hiatal hernia (Kohn et al, 2013). The Society noted that the general methodologic quality of available studies is low. Recommendations for indications for repair are as follows:

- "Repair of a type I hernia [sliding hiatal hernias, where the gastroesophageal junction migrates above the diaphragm] in the absence of reflux disease is not necessary" (moderate-quality evidence, strong recommendation).
- "All symptomatic paraesophageal hiatal hernias should be repaired [high-quality evidence, strong recommendation], particularly those with acute obstructive symptoms or which have undergone volvulus."
- "Routine elective repair of completely asymptomatic paraesophageal hernias may not always be indicated. Consideration for surgery should include the patient's age and co-morbidities" (moderate-quality evidence, weak recommendation).

Esophagogastroduodenoscopy

Preoperative endoscopy with esophagogastroduodenoscopy (EGD) can identify asymptomatic anatomical abnormalities that might influence surgical planning. In 2021, the ASMBS issued a position statement on the rationale for performance of upper gastrointestinal endoscopy before and after bariatric surgery (Campos et al, 2021). The ASMBS recommended preoperative EGD only be performed on patients with symptoms before bariatric surgery. The position statement also noted that while some abnormalities found during EGD do not change medical or surgical management, routine preoperative EGD is justifiable at the surgeon's discretion. Recently, the American Gastroenterological Association (AGA) has published a practice update on performing high-quality upper endoscopy confirming an appropriate indication for EGD, ensuring adequate visualization with mucosal cleansing and insufflation, and using a high-definition white-light endoscopy system (Nagula et al, 2024). The AGA guidance also endorses careful gastric mucosal inspection in anterograde and retroflexed views and documenting abnormalities using established classifications and standard terminology, whenever possible.

Coding

See the Codes table for details.

Description

Bariatric surgery is a treatment for obesity in patients who fail to lose weight with conservative measures. There are numerous gastric and intestinal surgical techniques available. While these techniques have heterogeneous mechanisms of action, the result is a smaller gastric pouch that

leads to restricted eating. However, these surgeries may lead to malabsorption of nutrients or eventually to metabolic changes.

Related Policies

- Gastric Electrical Stimulation
- Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

Forms of bariatric surgery performed without specific implantable devices are surgical procedures and, as such, are not subject to regulation by the FDA.

Table 1 shows forms of bariatric surgery with implantable devices approved by the FDA through the premarket approval process.

Table 1. FDA Approved Bariatric Surgery Devices

Device	Manufacturer	PMA Date	Labeled Indications
Obalon™ intragastric balloon system	Obalon Therapeutics, Inc.	Sept 2016	For use in obese adults (BMI, 30 to 40 kg/m^2) who have failed weight reduction with diet and exercise, and have no contraindications. Maximum placement time is 6 mo. Balloon is encased in a capsule. The capsule is swallowed and begins to dissolve after exposure to fluids in the stomach. After verification of capsule placement in the stomach, the balloon is filled with a gas mixture. Up to 3 balloons can be used during the 6 mo treatment period.
AspireAssist System®	Aspire Bariatrics	Jun 2016	For long-term use in conjunction with lifestyle therapy and continuous medical monitoring in obese adults >22 y, with a BMI of 35.0 to 55.0 kg/m^2 and no contraindications to the procedure who have failed to achieve and maintain weight loss with nonsurgical weight loss therapy.
ORBERA® intragastric balloon system	Apollo Endosurgery	Aug 2015	For use in obese adults (BMI, 30 to 40 kg/m^2) who have failed weight reduction with diet and exercise, and have no contraindications. Maximum placement time is 6 mo. Balloon placed endoscopically and inflated with saline.
LAP-BAND Adjustable Gastric Banding System	Apollo Endosurgery (original applicant: Allergan)	Apr 2010	For use in weight reduction for severely obese adults with BMI of at least 40 kg/m^2 or a BMI of at least 30 kg/m^2 with ≥1 severe comorbid conditions who have failed more conservative weight-reduction alternatives (e.g., supervised diet, exercise, behavior modification programs).
REALIZE Adjustable Gastric Band	Ethicon Endosurgery	Nov 2007	For use in weight reduction for morbidly obese patients and for individuals with BMI of at least 40 kg/m^2, or a BMI of at

Device	Manufacturer	PMA Date	Labeled Indications
			least 35 kg/m^2 with ≥1 comorbid conditions, or those who are ≥45.4 kg over their estimated ideal weight. Indicated for use only in morbidly obese adults who have failed more conservative weight-reduction alternatives (e.g., supervised diet, exercise, behavior modification programs).

BMI: body mass index: FDA: U.S. Food and Drug Administration; PMA: premarket approval.

In February 2017, the FDA issued a letter to health care providers discussing the potential risks with liquid-filled intragastric balloons in response to reports of 2 types of adverse events related to the balloons. Several dozen reports concerned spontaneous overinflation of the balloons, which caused pain, swelling, and vomiting. The second set of adverse event reports indicated that acute pancreatitis developed in several patients due to compression of gastrointestinal structures. These reports involved both ReShape (no longer marketed in the U.S.) and ORBERA brands. The adverse events may require premature removal of the balloons.

In August 2017, the FDA issued a second letter to health care providers informing them of 5 unanticipated deaths occurring from 2016 through the time of the letter, due to intragastric balloons. The FDA recommended close monitoring of patients receiving these devices. In June 2018, the FDA reported that, since 2016, a total of 12 deaths occurred in patients with liquid-filled intragastric balloons worldwide; 7 of these deaths were in patients in the U.S.

In April 2020, the FDA provided an update on risks and continued to recommend that healthcare providers "instruct patients about the symptoms of life-threatening complications such as balloon deflation, gastrointestinal obstruction, and gastric and esophageal perforation and monitor patients closely during the entire duration of treatment for potential complications, including acute pancreatitis, spontaneous hyperinflation, and other potentially life-threatening complications."

Esophagogastroduodenoscopy

Esophagogastroduodenoscopy (EGD) is useful for detecting conditions that may contraindicate bariatric surgery, such as malignancies. It assists in planning the appropriate bariatric procedure by identifying other gastrointestinal conditions like large hiatus hernia and peptic ulcer, which could impact surgery. EGD also detects conditions needing preoperative treatment, such as Helicobacter pylori infection. Moreover, endoscopy provides an anatomical assessment of the distal stomach, which becomes inaccessible after specific bariatric procedures.

Rationale

Background

Bariatric Surgery

Bariatric surgery is performed to treat obesity and obesity-related comorbid conditions. The first treatment of obesity is dietary and lifestyle changes. Although this strategy may be effective in some patients, only a few individuals with obesity can reduce and control weight through diet and exercise. Most patients find it difficult to comply with these lifestyle modifications on a long-term basis. When conservative measures fail, some patients may consider surgical approaches.

Literature Review

Bariatric Surgery in Adults With Obesity

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures

are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Esophagogastroduodenoscopy with Bariatric Surgery

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

Bariatric Surgery in Adults With Obesity

Clinical Context and Therapy Purpose

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is adults with a diagnosis of obesity.

Diagnosis is based on body mass index (BMI) plus clinical judgment. Clinicians are advised to consider age, gender, ethnicity, fluid status, and muscularity when evaluating individuals for weight management. Classification of overweight and obesity and associated risk of comorbidities is shown in Table 2. Lower BMI thresholds are recommended in South Asian, Southeast Asian, and East Asian adult populations (see Policy Guidelines).[2,]

Table 2. Overweight and Obesity Classification

Classification	Body Mass Index (kg/m^2)	Comorbidity Risk
Overweight	25.0-29.9	Increased
Class 1 obesity	30-34.9	Moderate
Class 2 obesity	35-39.9	Severe
Class 3 obesity	≥40	Very severe

Weight-related comorbidities are conditions caused by or exacerbated by excess weight. Clinical practice guidelines include a wide range of these conditions:

- Asthma
- Cardiovascular disease
- Certain types of cancer (e.g., colorectal cancer)
- Type 2 diabetes
- Dyslipidemia
- GERD
- Hypertension
- Infertility
- Male hypogonadism
- Mental health (depression)
- Metabolic syndrome
- Nonalcoholic fatty liver disease (nonalcoholic fatty liver and nonalcoholic steatohepatitis)
- Obstructive sleep apnea
- Osteoarthritis
- Polycystic ovarian syndrome
- Prediabetes
- Stroke
- Urinary stress incontinence

Interventions

The therapy being considered is any bariatric surgery procedure.

Open Gastric Bypass

The original gastric bypass surgeries were based on the observation that postgastrectomy patients tended to lose weight. The current procedure (CPT code 43846) involves both a restrictive and a malabsorptive component, with the horizontal or vertical partition of the stomach performed in association with a Roux-en-Y procedure (i.e., gastrojejunal). Thus, the flow of food bypasses the duodenum and proximal small bowel. The procedure may also be associated with an unpleasant "dumping syndrome," in which a large osmotic load delivered directly to the jejunum from the stomach produces abdominal pain and/or vomiting. The dumping syndrome may further reduce intake, particularly in "sweets eaters." Surgical complications include leakage and operative margin ulceration at the anastomotic site. Because the normal flow of food is disrupted, there are more metabolic complications than with other gastric restrictive procedures, including iron deficiency anemia, vitamin B12 deficiency, and hypocalcemia, all of which can be corrected by oral supplementation. Another concern is the ability to evaluate the "blind" bypassed portion of the stomach. Gastric bypass may be performed with either an open or laparoscopic technique.

Note: In 2005, CPT code 43846 was revised to indicate that the short limb must be 150 cm or less, compared with the previous 100 cm. This change reflects the common practice in which the alimentary (i.e., jejunal limb) of a gastric bypass has been lengthened to 150 cm. This length also serves to distinguish a standard gastric bypass with a very long, or very, very long gastric bypass, as discussed further here.

Laparoscopic Gastric Bypass

CPT code 43644 was introduced in 2005 and described the same procedure as open gastric bypass (CPT code 43846), but performed laparoscopically.

Laparoscopic Adjustable Gastric Banding

Adjustable gastric banding (CPT code 43770) involves placing a gastric band around the exterior of the stomach. The band is attached to a reservoir implanted subcutaneously in the rectus sheath.

Injecting the reservoir with saline will alter the diameter of the gastric band; therefore, the rate-limiting stoma in the stomach can be progressively narrowed to induce greater weight loss, or expanded if complications develop. Because the stomach is not entered, the surgery and any revisions, if necessary, are relatively simple.

Complications include slippage of the external band or band erosion through the gastric wall. Adjustable gastric banding has been widely used in Europe. Two banding devices are approved by the U.S. Food and Drug Administration (FDA) for marketing in the United States. The first to receive the FDA approval was the LAP-BAND® (original applicant, Allergan, BioEnterics, Carpinteria, CA; now Apollo Endosurgery, Austin, TX). The labeled indications for this device are as follows:

"The LAP-BAND system is indicated for use in weight reduction for severely obese patients with a BMI of at least 40 or a BMI of at least 35 with 1 or more severe comorbid conditions, or those who are 100 lb or more over their estimated ideal weight according to the 1983 Metropolitan Life Insurance Tables (use the midpoint for medium frame). It is indicated for use only in severely obese adult patients who have failed more conservative weight-reduction alternatives, such as supervised diet, exercise, and behavior modification programs. Patients who elect to have this surgery must make the commitment to accept significant changes in their eating habits for the rest of their lives."

In 2011, the FDA-labeled indications for LAP-BAND were expanded to include patients with a BMI from 30 to 34 kg/m^2 with at least 1 obesity-related comorbid condition.

The second adjustable gastric banding device approved by the FDA through the premarket approval process is the REALIZE® model (Ethicon Endo-Surgery, Cincinnati, OH). Labeled indications for this device are:

"The [REALIZE] device is indicated for weight reduction for morbidly obese patients and is indicated for individuals with a BMI of at least 40 kg/m^2, or a BMI of at least 35 kg/m^2 with 1 or more comorbid conditions. The Band is indicated for use only in morbidly obese adult patients who have failed more conservative weight-reduction alternatives, such as supervised diet, exercise, and behavior modification programs."

Open or Laparoscopic Sleeve Gastrectomy

A sleeve gastrectomy (SG; CPT code 43775) is an alternative approach to gastrectomy that can be performed on its own or in combination with malabsorptive procedures (most commonly biliopancreatic diversion [BPD] with duodenal switch [DS]). In this procedure, the greater curvature of the stomach is resected from the angle of His to the distal antrum, resulting in a stomach remnant shaped like a tube or sleeve. The pyloric sphincter is preserved, resulting in a more physiologic transit of food from the stomach to the duodenum and avoiding the dumping syndrome (overly rapid transport of food through the stomach into intestines) seen with distal gastrectomy. This procedure is relatively simple to perform and can be done as an open or laparoscopic procedure. Some surgeons have proposed the SG as the first in a 2-stage procedure for very high-risk patients. Weight loss following SG may improve a patient's overall medical status and, thus, reduce the risk of a subsequent more extensive malabsorptive procedure (e.g., BPD).

Open or Laparoscopic Biliopancreatic Diversion

The BPD procedure (also known as the Scopinaro procedure; CPT code 43847), developed and used extensively in Italy, was designed to address drawbacks of the original intestinal bypass procedures that have been abandoned due to unacceptable metabolic complications. Many complications were thought to be related to bacterial overgrowth and toxin production in the blind, bypassed segment. In contrast, BPD consists of a subtotal gastrectomy and diversion of the biliopancreatic juices into the distal ileum by a long Roux-en-Y procedure. The procedure consists of the following components:

- A distal gastrectomy induces temporary early satiety and/or the dumping syndrome in the early postoperative period, both of which limit food intake.

- A 200-cm long "alimentary tract" consists of 200 cm of ileum connecting the stomach to a common distal segment.
- A 300- to 400-cm "biliary tract" connects the duodenum, jejunum, and remaining ileum to the common distal segment.
- A 50- to 100-cm "common tract" is where food from the alimentary tract mixes with biliopancreatic juices from the biliary tract. Food digestion and absorption, particularly of fats and starches, are therefore limited to this small segment of bowel, creating selective malabsorption. The length of the common segment will influence the degree of malabsorption.

Because of the high incidence of cholelithiasis associated with the procedure, patients typically undergo an associated cholecystectomy.

Many potential metabolic complications are related to BPD, including, most prominently, iron deficiency anemia, protein malnutrition, hypocalcemia, and bone demineralization. Protein malnutrition may require treatment with total parenteral nutrition. Also, several case reports have noted liver failure resulting in death or liver transplant.

Open or Laparoscopic Biliopancreatic Diversion with Duodenal Switch

CPT code 43845, which specifically identifies the duodenal switch (DS) procedure, was introduced in 2005. The DS procedure is a variant of the BPD previously described. In this procedure, instead of performing a distal gastrectomy, a SG is performed along the vertical axis of the stomach. This approach preserves the pylorus and initial segment of the duodenum, which is then anastomosed to a segment of the ileum, similar to the BPD, to create the alimentary limb. Preservation of the pyloric sphincter is intended to ameliorate the dumping syndrome and decrease the incidence of ulcers at the duodeno-ileal by providing a more physiologic transfer of stomach contents to the duodenum. The SG also decreases the volume of the stomach and decreases the parietal cell mass. However, the basic principle of the procedure is similar to that of the BPD, i.e., producing selective malabsorption by limiting the food digestion and absorption to a short common ileal segment.

Vertical-Banded Gastroplasty

Vertical-banded gastroplasty (VBG; CPT code 43842) was formerly 1 of the most common gastric restrictive procedures performed in the United States but has now been replaced by other restrictive procedures due to high rates of revisions and reoperations. In this procedure, the stomach is segmented along its vertical axis. In order to create a durable reinforced and rate-limiting stoma at the distal end of the pouch, a plug of the stomach is removed, and a propylene collar is placed through this hole and then stapled to itself. Because the normal flow of food is preserved, metabolic complications are uncommon. Complications include esophageal reflux, dilation, or obstruction of the stoma, with the latter 2 requiring reoperation. Dilation of the stoma is a common reason for weight regain. Vertical-banded gastroplasty may be performed using an open or laparoscopic approach.

Vertical-banded gastroplasty (VBG) is a purely restrictive procedure that is largely not performed in the U.S. and has been replaced by laparoscopic adjustable gastric banding (LAGB) or sleeve gastrectomy (SG). Weight loss with VBG is substantial, but there are high rates of revisions and reoperations due to staple line disruption, perforation, band erosion or disruption, and stenosis at the band site. Overall rates of revisions and reoperations at up to 10 years may be as high as 50% (Balsiger et al, 2000, PMID11307094; Miller et al, 2007, PMID17116427). Vertical-banded gastroplasty is not included on the list of endorsed procedures by the American Society for Metabolic and Bariatric Surgery (https://asmbs.org/resources/endorsed-procedures-and-devices. Accessed January 3, 2024).

Long-Limb Gastric Bypass

Variations of gastric bypass procedures have been described, consisting primarily of long-limb Roux-en-Y procedures (CPT code 43847), which vary in the length of the alimentary and common limbs. For

example, the stomach may be divided with a long segment of the jejunum (instead of ileum) anastomosed to the proximal gastric stump, creating the alimentary limb. The remaining pancreaticobiliary limb, consisting of stomach remnant, duodenum, and length of proximal jejunum, is then anastomosed to the ileum, creating a common limb of variable length in which the ingested food mixes with the pancreaticobiliary juices. While the long alimentary limb permits absorption of most nutrients, the short common limb primarily limits absorption of fats. The stomach may be bypassed in a variety of ways (e.g., resection or stapling along the horizontal or vertical axis). Unlike the traditional gastric bypass, which is a gastric restrictive procedure, these very long-limb Roux-en-Y gastric bypasses combine gastric restriction with some element of malabsorptive procedure, depending on the location of the anastomoses. Note that CPT code for gastric bypass (43846) explicitly describes a short limb (<150 cm) Roux-en-Y gastroenterostomy and, thus, would not apply to long-limb gastric bypass.

Laparoscopic Malabsorptive Procedure

CPT code 43645 was introduced in 2005, to specifically describe a laparoscopic malabsorptive procedure. However, the code does not specifically describe any specific malabsorptive procedure.

Laparoscopic Gastric Plication

Laparoscopic gastric plication is a bariatric procedure that involves laparoscopic placement of sutures over the greater curvature (laparoscopic greater curvature plication) or anterior gastric region (laparoscopic anterior curvature plication) to create a tube-like stomach. To achieve gastric restriction the procedure requires 2 main steps, mobilization of the greater curvature of the stomach and suture plication of the stomach. CPT code 43843 Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty is commonly used for this procedure.

Comparators

Clinical practice guidelines recommend that comprehensive lifestyle intervention (CLI; i.e., interventions that combine behavioral, dietary, and physical activity components together, should always be provided in conjunction with other weight loss interventions). VA guidelines note that although there is insufficient evidence to recommend a specific number of sessions, most CLIs offer at least 12 intervention sessions in the first 12 months of intervention.

Outcomes

The general outcomes of interest are OS, change in disease status, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

Percent weight lost (e.g., proportions achieving 5%, 10%, and 15% weight loss or mean difference between groups) is commonly used in studies of interventions. Decrease in BMI can be used, especially if change leads to a change in risk category.

Recommended primary outcome measures are summarized in Table 3.

Table 3. Primary Outcome Measures for Bariatric Surgery Procedures

Outcome	Measures	Clinically Important Difference	Duration of Follow Up
Weight loss	% TBWL	•5% •FDA: varies (2% to 5%) depending on indication sought (weight loss, limited weight loss, or weight management) •Should be appropriate for associated risk •AACE: for tertiary prevention, based on comorbidities	12 months (6 months if indication is short-term weight loss)
	Responder rate	Proportion achieving at least 5% TBWL •Devices guidance - at least 50% of treated participants	12 months

Outcome	Measures	Clinically Important Difference	Duration of Follow Up
		•Drugs guidance - at least 35% and double the control group	
Adverse events	Incidence, severity	•Intervention-specific	12 months or longer

AACE: American Association of Clinical Endocrinology; FDA: Food and Drug Administration; TBWL: total body weight loss.

Indirect evidence of the effectiveness of weight loss interventions on health outcomes is provided by studies of the strength of the association between weight loss and health outcomes. AACE (2016) guidelines include a table of weight loss targets for clinical outcomes.[1,]

Direct evidence would come from studies of the effect of the intervention on health outcomes, preferably from randomized controlled trials.

The following secondary outcomes are of interest:

- Percent excess weight loss;
- Change in weight;
- Change in BMI (especially if decrease results in a change to a different risk group);
- Change in waist circumference;
- Patient-reported outcomes and patient preference information;
- Changes in weight-related comorbidities;

The existing literature evaluating any bariatric surgery procedure has varying lengths of follow-up, ranging from 1 to 3 years. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. One-year follow-up is necessary to demonstrate weight loss efficacy. Longer follow-up to 5 to 10 years is desirable to assess maintenance of weight loss, impact on co-occurring conditions, and appearance of long-term complications.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

Numerous systematic reviews have compared the efficacy of bariatric surgery with conservative therapy or compared different types of bariatric surgery techniques.[3,4,5,6,] Trials included in select systematic reviews can be compared in Appendix Table A1.

Many systematic reviews have reported improvements in specific obesity-related comorbidities following bariatric surgery. These reviews have relied primarily on the results of observational studies and included the outcomes of hypertension, type 2 diabetes (T2D), hyperlipidemia, cardiovascular events, quality of life, cancer, knee pain, and liver disease.[7,8,9,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,]

Nonrandomized Studies

Swedish Obese Subjects Trial

The Swedish Obese Subjects (SOS) trial is the most influential study of bariatric surgery versus conservative treatment. The SOS trial started in 1987 with a registry containing a detailed questionnaire and clinical data on obese patients with a BMI greater than 34 kg/m^2 at 480 primary health care centers in Sweden. From this registry, patients who met eligibility criteria were recruited and offered bariatric surgery. Thus, SOS patients self-selected into treatment, and there were baseline differences between groups, primarily reflecting more excess weight and a higher incidence of comorbidities in the surgery group. Participants with hypertension, diabetes, or lipid imbalances were eligible for inclusion, as well as those who had experienced a myocardial infarction or stroke more than six months prior to study inclusion. A total of 2010 people chose surgery, and 2037 people chose conservative care. Each surgical patient was matched on 18 clinical variables with a patient from the registry who received nonsurgical treatment (usual care). Each surgeon chose the surgical procedure offered. Most procedures were vertical-banded gastroplasty (VBG; >70%), with gastric bypass (6%) and gastric banding (23%) procedures performed as well. Usual care in the SOS trial was the local practice of the primary care center and usually did not include pharmacologic treatment. Patients were followed at regular intervals with repeat questionnaires and physical examinations for at least 10 years.

Many publications from this trial have reported on methods, weight loss, and clinical outcomes.[28,29,30,31,32,] The following general conclusions can be drawn from the SOS study:

- Weight loss was greater with bariatric surgery than with conservative treatment. At 10 years of follow-up, weight loss in the surgery group was 16% of total body weight compared with a weight gain of 1.6% in the conservative treatment group.
- There was significant improvement in glucose control for diabetics and reduced incidence of new cases of diabetes.
- The effect on other cardiovascular risk factors (e.g., hypertension, lipidemia) was also positive, but less marked than that seen for diabetes.
- Mortality was reduced by 29% after a mean follow-up of 10.9 years.
- Quality of life improved in the 2- to 10-year follow-up period, with the degree of improvement in quality of life correlating with the amount of weight loss.
- Bariatric surgery may greatly reduce the risk of cancer among patients with obesity and diabetes. Moreover, diabetes remission at the 10-year follow-up was associated with reduced cancer incidence (adjusted hazard ratio 0.40 [95% CI 0.22 - 0.74], p = 0.003).

Longitudinal Assessment of Bariatric Surgery Consortium

The Longitudinal Assessment of Bariatric Surgery Consortium study is a large prospective, longitudinal, noncomparative study of patients who underwent Roux-en-Y gastric bypass (RYGB) or laparoscopic adjustable gastric banding (LAGB) with follow-up through 3 years post-procedure.[33,] The study enrolled 2458 subjects, with a median BMI of 45.9 kg/m^2 (interquartile range [IQR], 41.7 to 51.5 kg/m^2). At baseline, 774 (33%) had diabetes, 1252 (63%) dyslipidemia, and 1601 (68%) hypertension. For their first bariatric surgical procedure, 1738 participants underwent RYGB, 610 LAGB, and 110 other procedures. At 3-year follow-up, for 1533 RYGB patients with available data, the percentage of baseline weight lost was 31.5% (IQR, 24.6% to 38.4%). For the 439 LAGB patients with available data at 3 years, the percentage of baseline weight loss was 15.9% (IQR, 7.9% to 23.0%). At 3 years post-surgery, 67.5% and 28.5% of RYGB and LAGB patients, respectively, had at least partial diabetes remission. Dyslipidemia was in remission in 61.9% and 27.1% of RYGB and LAGB patients, respectively. Subsequent bariatric procedures (revision or reversal) were required in 0.3% (95% confidence interval [CI], 0.1% to 0.9%) of the RYGB patients and in 17.5% (95% CI, 13.8% to 21.9%) of LAGB patients.

National Patient-Centered Clinical Research Network - Bariatric Study

The National Patient-Centered Clinical Research Network (PCORnet) Bariatric Study is a large retrospective, comparative study of 65,093 patients aged 20 to 79 years with BMI 35 kg/m^2 or greater who underwent RYGB (n=32,208), LAGB (n=29,693), or sleeve gastrectomy (SG) (n=3192) with follow-up through 5 years post-procedure.[34,]At baseline, patients across all three study groups suffered from several comorbid conditions, including hypertension (60%), dyslipidemia (49%), sleep apnea (49%), GERD (41%), diabetes (37%), and depression (31%). Mean estimated percent total weight loss (%TWL) was calculated at 1, 3, and 5 years in addition to 30-day rates of major adverse events. Study results are summarized in Table 4. This study demonstrates that RYGB is associated with a greater weight loss than SG (p<.001) and that LAGB is associated with the lowest amount of weight loss as observed in a large and diverse patient cohort.

Table 4. National Patient-Centered Clinical Research Network - Bariatric Study Results

	Mean TWL, % (95% CI)			MAE Rate,% (95% CI)
Group (n[a])	***1 Year***	***3 Years***	***5 Years***	***30 Days***
RYGB (19,029; 9225; 3676)	-31.2 (-31.3 to -31.1)	-29.0 (-29.2 to -28.8)	-25.5 (-25.9 to -25.1)	5.0 (NR)
LAGB (1681; 943; 337)	-13.7 (-14.0 to -13.3)	-12.7 (-13.5 to -12.0)	-11.7 (-13.1 to -10.2)	2.9 (NR)
SG (14,929; 5304; 1088)	-25.2 (-25.4 to -25.1)	-21.0 (-21.3 to -20.7)	-18.8 (-19.6 to -18.0)	2.6 (NR)

CI: confidence interval; LAGB: laparoscopic adjustable gastric banding; MAE: major adverse event; NR: not reported; RYGB: Roux-en-Y gastric bypass; SG: sleeve gastrectomy; TWL: total weight loss.
[a] Number of patients evaluated at 1, 3, and 5 years, respectively.

Evidence for Specific Types of Bariatric Surgery Procedures

Arterburn et al (2021) published a retrospective, matched cohort study to investigate weight loss among patients with severe obesity undergoing RYGB, SG, or nonsurgical treatment.[35,] Among 17,258 RYGB, 13,900 SG, and 87,965 nonsurgical patients, the 5-year follow-up rate was 72.0%, 70.9%, and 64.5%, respectively. At 1, 5, and 10 years, RYGB patients had a %TWL of -28.35% (95% CI, -28.53 to -28.18), -21.74% (95% CI, -22.02 to -21.45), and -20.18% (95% CI, -21.00 to -19.34), respectively; at the same time points, nonsurgical patients had a %TWL of -0.22% (95% CI, -0.35 to -0.09), -2.24% (95% CI, -2.46 to -2.02), and -4.78% (95% CI, -5.51 to -4.04), respectively. At 1 and 5 years, SG patients had a %TWL of -22.98% (95% CI, -23.19 to -22.76) and -15.99% (95% CI, -16.58 to -15.40), respectively.

Wadden et al (2019) reported on end-of-trial results from the Look AHEAD: Action for Health in Diabetes (Look AHEAD) trial, which evaluated outcomes in patients with T2D and obesity who had self-selected to receive bariatric surgery after failing an assigned intensive lifestyle intervention (ILI) or a diabetes support and education (DSE) control therapy.[36,] Patients who received bariatric surgery were significantly more likely to be female (p<.001), younger (p<.001), and have higher BMI at randomization (p<.001). Patients underwent 127 RYGB, 58 LAGB, and 11 SG procedures, respectively. End-of-trial assessments were completed at 4.3 years post-surgery compared to 9.6 years post-randomization for the DSE and ILI participants. Patients undergoing RYGB, LAGB, or SG surgical procedures lost a mean of 22.4% ± 1.0%, 13.0% ± 1.5%, and 16.2% ± 3.3% of baseline weight, respectively. Twelve patients (6.1%) receiving bariatric surgery were randomized with a BMI <35 kg/m^2. The mean BMI was 37.0 ± 5.1, 37.1 ± 5.3, and 42.1 ± 5.8 for DSE, ILI, and surgery groups, respectively (p<.001). Overall, surgically-treated patients lost a mean of 19.3% of baseline weight, compared with 5.8% and 3.3% for the ILI and DSE participants. Full diabetes remission was achieved by 7.6% of bariatric surgery participants compared to 1.1% of ILI and 1.1% of DSE participants. Full remission was significantly more common in surgically treated participants in ILI (RR 6.72; 95% CI, 3.35 to 13.48; p<.001) or DSE (RR 7.07; 95% CI, 3.49 to 14.30; p<.001) groups. Significantly greater reductions in waist circumference (p<.001), triglyceride levels (ILI: p=.03; DSE: p=.02), and hemoglobin A1c (HbA1c) levels (p<.001) were observed in surgically-treated patients compared to ILI or DSE groups. The study was limited by heterogeneity in baseline characteristics and choice of surgical procedure. Results were not stratified by surgery type or BMI range.

Laparoscopic Adjustable Gastric Banding

Systematic Reviews

A 2006 TEC Assessment updated the evidence on LAGB and compared outcomes with gastric bypass.[37,] This Assessment concluded that, for patients considering bariatric surgery, there was sufficient evidence to permit an informed choice between gastric bypass and LAGB. An informed patient might reasonably choose open gastric bypass or LAGB as the preferred procedure. Preoperative counseling should include education on the comparative risks and benefits (e.g., extent of weight loss and frequency and timing of potential complications) of the 2 procedures to optimize choice based on preferences and shared decision making.

Weight loss outcomes from the studies reviewed in the Assessment confirmed that weight loss at 1 year was lower for LAGB than for open gastric bypass. The percentage of excess weight loss (EWL) at 1 year was approximately 40%, compared with 60% or higher for open gastric bypass. At time points beyond 1 year, some comparative studies have reported that the difference in weight loss between LAGB and open gastric bypass narrows, but other studies did not. Weight loss outcomes from the 9 single-arm series with the most complete follow-up did not support the hypothesis that the difference in weight loss shrinks after 1 to 2 years of follow-up. It appears more likely from the current data that attrition bias might have accounted for the diminution of the difference in weight loss over time, particularly when patients with bands removed or deflated were excluded from analysis.

These studies also confirmed that short-term (perioperative) complications are very low with LAGB and lower than with open gastric bypass or LAGB. Death was extremely rare, and serious perioperative complications probably occurred at rates less than 1%. The reported rates of long-term adverse events vary considerably. In the comparative trials, reoperations were reported in approximately 25% of patients, while, in the single-arm studies, the composite rate for reoperations were approximately 50% lower (11.9%). The rates of other long-term complications were also highly variable; e.g., the range of rates for band slippage was 1% to 36%, and the range for port access problems was 2% to 20%. These data on long-term complications remain suboptimal. The reporting of long-term complications in these trials was not systematic or consistent. While impossible to determine the precise rates of long-term complications from these data, it is likely that complications have been underreported in many studies due to incomplete follow-up and lack of systematic surveillance. A publication by Ibrahim et al (2017) reviewed 25,042 Medicare beneficiaries who underwent LAGB surgery; 18.5% (n=4636) patients underwent 1 or more reoperation(s). Reoperation was prompted by the need for band removal (41.8%), band and port replacement (28.6%), and other requirements.[38,] The rates of long-term complications reported in some studies raise concern about the impact of these events on the overall benefit-risk profile for LAGB.

In comparing LAGB with open gastric bypass, there are tradeoffs in terms of risks and benefits. LAGB is a less invasive procedure associated with fewer procedural complications, decreased hospital stay and earlier return to usual activities. However, benefits defined by the amount of weight lost are lower for LAGB. The patterns of long-term complications also differ between the 2 procedures. For LAGB, longer-term adverse events related to the presence of a foreign body in the abdomen will occur and result in reoperations and removal of the band in a minority of patients. Patients who have their bands removed can later be offered an alternative bariatric surgery procedure, such as gastric bypass.

A systematic review by Chakravarty et al (2012)[39,] comparing LAGB with other bariatric surgery procedures drew conclusions similar to the TEC Assessment. Reviewers included 5 RCTs. The RCTs found that patients using LAGB lost weight, but less weight than with other procedures (e.g., gastric bypass or SG). However, the short-term complication rate was lower with LAGB, and no difference was found in quality of life after LAGB versus other procedures.

Prospective Studies

Dixon et al (2018) published a prospective, industry-sponsored study of morbidly obese patients who underwent implantation of the adjustable gastric banding system (LAP-BAND)[40,]. Between 2009 and 2013, 652 patients with a mean BMI of 45.4 kg/m^2 were treated at 17 participating centers in the United States and Canada. At 5 years, the explant rate was 8.74% (95% CI, 6.6 to 10.9). Excluding explants, 100 (15.3%) reoperations were necessary during the follow-up period. A mean weight loss of 18.7% was achieved by 2 years and maintained through 5-year follow-up. The study was limited by the lack of control group.

Sleeve Gastrectomy

Systematic Reviews

Sleeve gastrectomy may be performed as a stand-alone procedure or in combination with a malabsorptive procedure, such as the BPD with BPD-DS. It has also been proposed as the first step in a 2-stage procedure, with gastric bypass or BPD as the second stage.

Numerous recent systematic reviews have compared SG and RYGB with regard to effects on weight, comorbidities, and complications (Tables 5 and 6).[41,42,43,44,45,46,]

Lee et al (2021) performed a meta-analysis evaluating long-term (5 years) outcomes of laparoscopic RYGB versus SG.[47,] A total of 33 studies (N=2475) were included. Results demonstrated that RYGB resulted in a significantly greater decrease of BMI compared to SG at 1 and 3 years post-surgery; results at 5 years did not reach statistical significance. A similar trend was seen for the resolution of dyslipidemia. Furthermore, neither RYGB nor SG was superior for the remission of T2D and hypertension at 5 years. Recent meta-analyses have provided further insights into the long-term remission rates of diabetes and hypertension between these bariatric procedures. A meta-analysis conducted by Elsaigh et al (2024), encompassing 23 RCTs (N=4148), revealed that RYGB significantly improved diabetes remission and resulted in greater total body weight loss compared to SG at up to 10 years of follow-up. However, heterogeneity was observed under sub-group analysis at this study period (p=.001, I^2=75%).[48,] In another recent meta-analysis of 11 RCTs (N=2323), Zevallos et al. (2024) examined the remission of hypertension after SG versus RYGB. Their findings showed a notable difference in hypertension remission rates at ≥ 5 years, favoring RYGB (relative risk: 1.39, 95% CI 1.06-1.82, p=.02).[49,]

Gu et al (2020) completed a meta-analysis of the medium- and long-term effects of laparoscopic SG and RYGB.[41,] The evaluation included 9038 patients from 28 studies. Overall, 5 year follow-up results revealed that laparoscopic RYGB was associated with an improvement in percentage of EWL and remission of T2D, hypertension, and dyslipidemia as compared to laparoscopic SG. Han et al (2020) also published a systematic review and meta-analysis involving 18 studies (N=2917) that compared weight loss and comorbidity resolution between laparoscopic SG and RYGB.[42,] Results from this analysis revealed no significant difference in EWL or T2D resolution between the 2 procedures. Laparoscopic RYGB was found to be superior to SG with regard to dyslipidemia, hypertension, and gastroesophageal reflux disease (GERD) management; however, patients who underwent laparoscopic SG experienced fewer postoperative complications and reoperation rates. Similarly, in an updated meta-analysis by Memon et al (2024) of 5 RCTs (N=1093) of postoperative GERD data comparing laparoscopic SG and laparoscopic RYGB in adults, SG was associated with increased adverse GERD outcomes compared to RYGB at 5 years.[50,]Overall, SG was associated with significantly more interventions (both medical and surgical) for either worsening GERD and/or development of de novo GERD compared to RYGB (odds ratio 5.98, 95% CI 3.48-10.29; p≤.01; I^2 =0%) Moderate level of certainty).

Sharples et al (2020) performed a systematic review and meta-analysis evaluating long-term (5 years) outcomes of RYGB and SG.[43,] Overall, both RYGB and SG resulted in sustained weight loss and comorbidity control with RYGB associated with a greater percent EWL and improved dyslipidemia outcomes.

Shenoy et al (2020) published a systematic review and meta-analysis of 9 studies that compared laparoscopic SG (LSG) and RYGB in 2240 elderly (>55 years) patients.[44,] Results revealed no significant differences between the 2 bariatric procedures with regard to the rate of early complications (3.6% LSG vs. 5.8% RYGB; p=.15) and mortality (0.1% vs. 0.8%; p=.27). Additionally, there was no difference in EWL between the procedures at 1 year; however, the authors recommended SG for high-risk elderly patients due to the reduced mortality and complication rates with this procedure. Another systematic review and meta-analysis by Xu et al (2020) involving 19 studies also concluded that SG was the preferable option for obese patients 60 years and older as it was found to be non-inferior to RYGB with regard to efficacy but overall had an improved safety profile.[51,]

Osland et al (2017) published a systematic review and meta-analysis of RCTs comparing laparoscopic vertical SG with RYGB.[52,] The literature search, conducted from 2000 to November 2015, identified 9 RCTs for inclusion (N=865 patients). Four trials were included in meta-analyses comparing percent EWL between the 2 groups. Results at both 6- and 12-month follow-ups showed that the procedures are comparable. Osland et al (2020) recently published a continuation of their work that focused exclusively on long-term (5 year) weight outcomes of laparoscopic vertical SG versus RYGB.[53,] This systematic review and meta-analysis included 5 studies (SG=520; RYGB=508) and results revealed that a statistically significant BMI loss was seen with both SG: -11.37 kg/m^2 (range, -6.3 to -15.7) and RYGB: -12.6 kg/m^2 (range, -9.5 to -15.4) at 5 years. However, differences in reporting parameters limit the ability to reliably compare outcomes using statistical methods and the results may have been impacted by large dropout rates and per protocol analyses of the 2 largest included studies.

A systematic review by Juodeikis and Brimas (2017) summarized evidence on long-term results after SG.[54,] Reviewers included an RCT and 19 retrospective studies, with a total of 2713 patients who received SG. Mean preoperative BMI was 46.9 kg/m^2. Mean duration of follow-up ranged from 5 to 11 years, and mean proportion of patients followed for 5 years was 68.5%. Seventeen studies (N=1501 patients) reported 5-year follow-up data. At 5 years, resolution of T2D, arterial hypertension, dyslipidemia, obstructive sleep apnea (OSA), and degenerative joint diseases also improved in most patients. Two studies reported weight loss after 7 and 8 years; percent EWL rates were 56.6% and 54.8%, respectively.

In a meta-analysis of 21 randomized and nonrandomized studies (N=18,766 patients) comparing SG with laparoscopic RYGB for morbid obesity, Zhang et al (2015) reported no significant difference in percent EWL from 0.5- to 1.5-year follow-ups.[55,] However, after 1.5 years, RYGB was associated with higher percent EWL (2-year mean difference [MD], 5.77; 95% CI, 4.29 to 7.25; p<.05). Adverse events were more frequent following RYGB (odds ratio [OR] for major complication, 1.29; 95% CI, 1.22 to 3.22; p<.01).

Trastulli et al (2013) conducted a systematic review of 15 RCTs (N=1191 patients) that compared SG with other bariatric procedures.[56,] Summary statistics were provided; meta-analyses were not conducted. Reviewers reported mean complication rates with SG of 12.1% (range, 10% to 13.2%) compared with 20.9% with LAGB (range, 10% to 26.4%). Percent EWL ranged from 49% to 81% with SG and from 62.1% to 94.4% with LAGB.

Brethauer et al (2009) reviewed 36 studies (N=2570 patients) in a systematic review of SG as a staged and primary procedure, the largest trials coming from European centers.[57,] Thirteen studies (n=821 patients) reported on high-risk patients having a staged approach and 24 studies (n=1749 patients) on SG as the primary procedure. Mean percent EWL, reported in 24 studies (n=1662 patients), was 55.4% overall. Mean postoperative BMI, reported in 26 studies (n=1940 patients), decreased from a baseline of 51.2 to 37.1 kg/m^2. Other studies reported weight loss in terms of BMI decrease, the percentage of BMI lost, or percentage of total weight lost; all had significant reductions from baseline. Rates of major postoperative complications ranged from 0% to 23.8% for all studies and from 0% to 15.3% in studies with more than 100 patients. Leaks (2.2%), bleeding episodes requiring reoperation (1.2%), and postoperative strictures requiring endoscopic or surgical

intervention (0.6%) were reported in the 33 studies (n=2570 patients). All extracted studies reported mortality data, with 5 deaths within 30 days of surgery (overall mortality rate, 0.19%; 2 in the high-risk/staged group, 3 in the primary procedure group).

Table 5. Systematic Review Characteristics for Sleeve Gastrectomy

Study	Dates	Studies	Participants	Design	Duration
Lee et al (2021) [47]	Through Jan 2019	33	SG=1252; RYGB=1223	RCTs	1 to 5 y
Gu et al (2020) [41]	Through Jan 2019	28	SG=4597; RYGB=4441	7 RCTs; 6 prospective; 15 retrospective	3 to 7 y
Han et al (2020) [42]	Through Jan 2020	18	2917	9 RCTs; 9 nonrandomized studies of interventions	1 to 82.2 mo
Sharples et al (2020) [43]	Through Dec 2018	5	729	RCTs	5 y
Shenoy et al (2020) [44]	1991 to 2019	9	SG=683; RYGB=1557	RCTs; observational studies	Minimum follow-up: 1 y
Osland et al (2017) [52]	2000 to Nov 2017	9	SG=437; RYGB=428	RCTs	3 mo to 5 y
Juodeikis et al (2017) [54]	Through May 2016	20	1626	1 RCT; 19 retrospective	5 to 11 y
Zhang et al (2015) [55]	Through Oct 2013	21	18,766	8 RCTs; 13 nonrandomized comparative	1 to 5 y
Trastulli et al (2013) [56]	Through Nov 2012	15	1191	RCTs	6 mo to 3 y
Brethauer et al (2009) [57]	1996 to 2009	36	2570	2 RCTs; 1 cohort; 33 case series	3 mo to 5 y

RCT: randomized controlled trial; RYGB: Roux-en-Y gastric bypass; SG: sleeve gastrectomy.

Table 6. Systematic Review Results for Sleeve Gastrectomy

Study	BMI mean difference (95% CI)	Comorbidities (95% CI)
Lee et al (2021) [47]	Mean difference SG vs RYGB: 1 y (16 trials): -1.25 kg/m^2 (-2.01 to -0.49) 3 y (5 trials): -1.71 kg/m^2 (-2.68 to -0.74) 5 y (4 trials): -1.46 kg/m^2 (-3.15 to 0.23)	Remission, SG vs RYGB: T2D (1 y): RR, 0.86 (0.71 to 1.04) T2D (3 y): RR, 0.88 (0.72 to 1.07) T2D (5 y): RR, 0.79 (0.57 to 1.10) Hypertension (5 y): RR, 0.86 (0.68 to 1.10) Dyslipidemia (5 y): RR, 0.68 (0.46 to 1.23)
	Percent EWL (95% CI)	**Comorbidities (95% CI)**
Gu et al (2020) [41]	Weighted mean difference, RYGB and SG: 3 y (13 trials): -4.37 (-8.10 to -0.64) 5 y (9 trials): -2.20 (-3.83 to -0.57)	Remission, RYGB and SG: T2D (3 y): OR, 0.68 (0.48 to 0.95) T2D (5 y): OR, 0.63 (0.41 to 0.96) Hypertension (5 y): OR, 0.51 (0.38 to 0.68) Dyslipidemia (5 y): OR, 0.3 (0.19 to 0.48)
Han et al (2020) [42]	Mean difference, RYGB and SG: RCTs: -0.16 (-0.52 to 0.19)	Resolution, RYGB and SG: T2D: RR, 1.07 (0.89 to 1.28) Dyslipidemia: RR, 1.36 (1.17 to 1.59) Hypertension: RR, 1.23 (1.04 to 1.45) symptoms: RR, 0.16 (0.06 to 0.44)
Sharples et al (2020) [43]	5 y: RYGB: 65.7% SG: 57.3%	RYGB vs. SG at 5 y: T2D resolution: 37.4% vs. 27.5% Diabetes improvement: 77.5% vs. 74% Hypertension resolution: 60.1% vs. 48.4% Hypertension improvement: 86.4% vs. 76.6% Dyslipidemia resolution: 68.6% vs. 55.2% remission: 60.4% vs. 25%
Shenoy et al (2020) [44]	Mean difference, RYGB and SG: -7.79 (-23.96 to 8.38)	Resolution, RYGB and SG: T2D (5 studies): OR, 1.02 (0.63 to 1.66)

Study	BMI mean difference (95% CI)	Comorbidities (95% CI)
		Hypertension (4 studies): OR, 0.57 (0.35 to 0.93) Obstructive sleep apnea (2 studies): OR, 1.14 (0.55 to 2.34)
Osland et al (2017)[52,]	Mean difference, SG and RYGB: 6 mo (3 trials): 0.5 (-5.0 to 6.0) 12 mo (2 trials): 7.6 (-0.1 to 15.3)	NR
Juodeikis et al (2017)[54,]	Mean rates for SG: 5 y (17 trials): 58.4% 7 y (2 trials): 56.6% 11 y (1 trial): 62.5%	Remission/improvement: T2D: 77.8% Hypertension: 68.0% Dyslipidemia: 65.9% Sleep apnea: 75.8%
Zhang et al (2015)[55,]	Mean difference, RYGB and SG: 6 mo (9 studies): 0.2 (-2.5 to 2.9) 12 mo (15 studies): 2.9 (-0.2 to 6.0) 4 y (3 studies): 2.7 (0.2 to 5.2)	Mean difference resolution, RYGB and SG: T2D (10 studies): 3.3 (2.0 to 5.5) Hypertension (10 studies): 1.3 (0.7 to 2.4) Dyslipidemia (5 studies): 1.1 (0.3 to 1.3) Sleep apnea (7 studies): 1.5 (0.8 to 2.6)
Trastulli et al (2013)[56,]	Mean by procedure: SG: 49% to 81% LGB: 62% to 94% LAGB: 29% to 48%	T2D: SG, 67% to 100% LGB, 80% to 100%
Brethauer et al (2009)[57,]	Mean rate overall for SG: 55% (range, 33% to 85%)	Remission/improvement: T2D: >70% Significant reductions also seen in hypertension, hyperlipidemia, and sleep apnea

BMI: body mass index; CI: confidence interval; EWL: excess body weight loss; LAGB: laparoscopic adjustable gastric banding; LGB: laparoscopic gastric bypass; NR: not reported; OR: odds ratio; RCT: randomized controlled trial; RR: relative risk; RYGB: Roux-en-Y gastric bypass; SG: sleeve gastrectomy; T2D: type 2 diabetes.

Randomized Controlled Trials

Hofso et al (2019) published the results of a single-center, triple-blind RCT comparing the efficacy of RYGB (n=54) versus SG (n=55) on diabetes remission and ß-cell function in patients with obesity and T2D.[58,] Inclusion criteria included previously verified BMI ≥35 kg/m^2 and current BMI ≥33.0 kg/m^2, HbA1c ≥6.5% or use of antidiabetic medications with HbA1c ≥6.1%, and age ≥18 years. One-year follow-up was completed by 107 (98%) of 109 patients, with 1 patient in each group withdrawing after surgery. In the intention-to-treat population, diabetes remission rates were superior in the gastric bypass group than in the SG group (risk difference 27%; 95% CI, 10 to 44; RR 1.57, 95% CI, 1.14 to 2.16; p=.0054). Results were similar in the per-protocol population (risk difference 27%; 95% CI, 10 to 45; RR 1.57; 95% CI, 1.14 to 2.15; p=.0036). The 2 procedures had a similar beneficial effect on ß-cell function. Peterli et al (2018) published a randomized study of adults with morbid obesity treated with either LSG or RYGB.[59,] Two hundred five patients (mean age, 45.5 years; mean BMI, 43.9; 72% women) treated at 4 Swiss bariatric centers were randomly assigned to receive SG (n=101) or RYGB (n=104) with 5-year follow-up. Excess BMI loss was 61.6% for SG and 68.3% for RYGB (95% CI, -14.30 to -0.06; p=.22). Gastric reflux remission was seen in 25.0% of SG and 60.4% of RYGB patients. Reoperations or interventions were necessary for 16/101 (15.8%) in the SG group and 23/104 (22.1%) of the RYGB group. The study was limited by the lack of analysis of diabetes remission information, and the results may not be generalizable.

Salminen et al (2018) published a randomized trial, Laparoscopic Gastric Bypass vs. Laparoscopic Sleeve Gastrectomy in the Treatment of Morbid Obesity (SLEEVEPASS), comparing 5-year outcomes of morbidly obese patients (n=240; mean age, 48 years; mean baseline BMI, 45.9; 69.6% women) who underwent either LSG (n=121) or RYGB (n=119).[60,] Five-year estimated mean percentage excess BMI loss was 49% (95% CI, 45 to 52) for SG and 57% (95% CI, 53 to 61) for gastric bypass. For SG and RYGB, respectively, rates of remission of T2D were 37% (n=15/41) and 45% (n=18/40; p>.99). Medication for hypertension was discontinued in 20/68 (29%) SG patients and 37/73 (51%) RYGB patients (p=.02). Overall 5-year morbidity rate was 19% for SG and 26% for RYGB (p=.19), and there was no significant

difference in quality of life between groups (p=.85). The study was limited by the following: (1) only a small number (n=430) of bariatric procedures were performed in Finland at trial initiation in 2008, meaning a learning curve could account for some earlier technical complications, (2) the study had a higher reoperation rate for SG than other trials reported, (3) approximately 20% of patients were lost to follow-up, and (4) there was a lack of reliable information for diabetes duration at baseline.

Wolnerhanssen et al (2021) pooled 5-year outcomes data from the 2018 studies by Peterli et al and Salminen et al.[61,] Five-year follow-up was available for 199 of 228 patients after SG and 199 of 229 after RYGB. Patients who underwent SG had an estimated 7% greater excess BMI loss versus RYGB (p<.001). While remission rates for hypertension were better after RYGB versus SG (60.3% vs. 44.9%; p<.049), between-group differences in rates of remission of T2D, OSA, or quality of life scores did not reach statistical significance. The rate of complications was higher after RYGB versus SG (37.2% vs 22.5%; p=.001), but there was no difference in mean Comprehensive Complication Index value (30.6 vs. 31.0 points; p=.859).

An RCT comparing short-term outcomes of laparoscopic SG with gastric bypass was published in 2012.[62,] Trialists compared 30-day outcomes for 117 patients randomized to gastric bypass with 121 patients randomized to LSG. The rate of major complications (no deaths in either group) was 9.4% in the gastric bypass group compared with 5.8% in the LSG group (p=.29). Minor complications were more common in the gastric bypass group than in the LSG group (17.1% vs. 7.4%, p=.02), as were combined major and minor complications (26.5% vs. 13.2%, p=.01).

Karamanakos et al (2008) carried out a double-blind RCT comparing outcomes of laparoscopic RYGB and LSG on body weight, appetite, fasting, and postprandial ghrelin and peptide YY (levels at 1, 3, 6, and 12 months after surgery).[63,] Thirty-two patients were randomized, half to each procedure. The decrease in body weight and BMI were marked and comparable in each group. EWL was greater after LSG than laparoscopic RYGB at 6 months (55.5% vs. 50.2%; p=.04) and 12 months (69.7% vs. 60.5%; p=.05), all respectively. Fasting peptide YY levels increased after both surgical procedures. Appetite decreased in both groups but decreased more after LSG.

Himpens et al (2006) reported on a randomized trial comparing LAGB with isolated LSG in 80 patients and reported 3-year follow-up.[64,] Median baseline BMI was 37 kg/m^2 (range, 30 to 47) in the LAGB group and 39 kg/m^2 (range, 30 to 53) in the SG group. Outcomes of weight loss, feeling of hunger, sweet-eating, complications, and reoperations were recorded at 1- and 3-year follow-ups. Median decrease in BMI in the gastric bypass group was 15.5 kg/m^2 (range, 5 to 39) after 1 year and 18 kg/m^2 (range, 0 to 39) at 3 years after LAGB. One year after SG, decrease in BMI was 25 kg/m^2 (range, 0 to 45) and 27.5 kg/m^2 (range, 0 to 48) after 3 years. Median EWL in the LAGB group was 41.4% after 1 year and 48% at 3 years. Median EWL after SG was 58% and 66% at 1 and 3 years, respectively. More patients having SG than LAGB reported a loss of craving for sweets, but the difference was not statistically significant; appeared de novo in more SG than LAGB patients at 1 year, and the relation reversed at 3 years; between-group differences were not statistically significant at either time point. Two SG patients required reoperation for complications. Seven late complications required reoperation after LAGB, including pouch dilations treated by band removal (n=2) or conversion to RYGB (n=1), 1 gastric erosion treated by conversion to RYGB, and 3 system disconnections that required reconnection. Four patients had reoperations for lack of efficacy (2 LAGB patients underwent conversion to RYGB, 2 SG patients underwent conversion to DS). The trialists noted that the number of reoperations was significant in both groups and that the severity of complications was greater in the SG group.

Biliopancreatic Diversion With Duodenal Switch

Systematic Reviews

In an evidence-based review of literature, Farrell et al (2009) summarized data on BPD with or without DS, RYGB (proximal), and LAGB, and reported that at a mean 1-year follow-up, EWL for BPD with or without DS (outcomes with and without DS not reported separately) was 72% (4 studies;

n=896 patients), 67% for RYGB (7 studies; n=1627 patients), and 42% for LAGB (11 studies; n=4456 patients).[65,] At mean follow-up of 5 years, EWL for BPD with or without DS was 73% (3 studies; n=174 patients), 58% for RYGB (3 studies; n=176 patients), and 55% for LAGB (5 studies; n=640 patients). Reviewers noted that "given the marked paucity of prospectively collected comparative data among the different bariatric operations, it remains impossible to make definitive recommendations for one procedure over another."

Esparaham et al. (2024) conducted a meta-analysis of 12 studies (N=2678) with follow-up periods ranging from 1 to 15 years, to evaluate the comparative outcomes of DS and RYGB in individuals with a BMI of ≥50 kg/m^2.[66,] The findings indicated that DS resulted in significantly more substantial reductions in BMI and overall weight loss within this cohort when compared to RYGB. However, DS was linked to a higher incidence of major malnutrition (8.3% vs. 1.2% in RYGB; OR: 5.53, 95% CI: 1.35-22.44, p=.02), as well as an increased risk of developing gallbladder disease requiring cholecystectomy (24.6% vs. 4.5% post-RYGB; OR: 6.36, 95% CI: 1.70–23.82, p=.01).

Randomized Controlled Trials

Salte et al (2024) conducted an open-label RCT (N=60) at two academic bariatric centers in Sweden and Norway.[67,] The study aimed to compare long-term outcomes, specifically weight loss, health parameters, and quality of life following either DS or RYGB surgeries in patients with a body mass index (BMI) of 50 to 60kg/m^2. Forty-eight (of 60) patients (80%) were assessed after a median of 12 (range, 9-13) years. At follow-up, the mean BMI reductions were 20.3 (95% CI, 17.6-23.0) for DS and 11.0 (95% CI, 8.3-13.7) for RYGB, with a mean between-group difference of 9.3 (95% CI, 5.4-13.1; p<.001). Total weight loss was 33.9% (95% CI, 27.8%-40.0%) for DS and 20.0% (95% CI, 15.3%-24.7%) for RYGB (p=.001).

Mean serum lipid levels, except high-density lipoprotein cholesterol and HbA1c, improved more in the DS group during follow-up. Bone mass was reduced for both groups from 5 to 10 years, with lower bone mass after DS at 10 years. Quality-of-life scores (Obesity-Related Problem Scale and the 36-Item Short Form Health Survey) were comparable across groups at 10 years. The total number of adverse events was higher after DS (135 vs 97 for RYGB; p=.02). More patients in the DS group developed vitamin deficiencies (21 vs 11 for RYGB; p=.008) and 4 (of 29) patients in the DS group (14%) developed severe protein caloric malnutrition, of whom 3 (10%) underwent revisional surgery. These findings indicate that while DS facilitates more significant BMI reduction over time and offers some cardiometabolic advantages, it also incurs nutritional deficiencies and adverse effects. The small sample size is a notable limitation, suggesting that the evaluation of several outcomes should be approached with caution.

Bariatric Surgery for Adults with Class 1 Obesity and Type 2 Diabetes

Clinical Context and Therapy Purpose

The purpose of gastric bypass, SG, BPD, and adjustable gastric banding is to provide treatment options that are alternatives to or improvements on existing therapies, such as standard medical care, in patients who have Class 1 obesity and T2D.

Resolution (cure) or improvement of T2D after bariatric surgery and observations that glycemic control may improve immediately after surgery before a significant amount of weight is lost have promoted interest in a surgical approach to the treatment of T2D. The various surgical procedures have different effects, and gastrointestinal rearrangement seems to confer additional antidiabetic benefits independent of weight loss and caloric restriction. The precise mechanisms are not clear, and multiple mechanisms may be involved. Gastrointestinal peptides (e.g., glucagon-like peptide-1, glucose-dependent insulinotropic peptide, and peptide YY) are secreted in response to contact with unabsorbed nutrients and by vagally mediated parasympathetic neural mechanisms. Glucagon-like peptide-1 is secreted by the L cells of the distal ileum in response to ingested nutrients and acts on pancreatic islets to augment glucose-dependent insulin secretion. It also slows gastric emptying, which delays digestion, blunts postprandial glycemia, and acts on the central nervous system to

induce satiety and decrease food intake. Other effects may improve insulin sensitivity. Glucose-dependent insulinotropic peptide acts on pancreatic beta cells to increase insulin secretion through the same mechanisms as glucagon-like peptide-1, although it is less potent. Peptide YY is also secreted by the L cells of the distal intestine and increases satiety and delays gastric emptying.
The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals who have Class 1 obesity and T2D.

Interventions
The therapy being considered is gastric bypass, SG, BPD, and adjustable gastric banding. Current indications for bariatric surgery view poorly or uncontrolled T2D as a comorbidity whose presence supports the need for surgery in individuals with a BMI of less than 35 kg/m^2.

Comparators
Comparators of interest include standard medical care. Treatment for individuals with T2D includes blood glucose regulation and insulin therapy.

Outcomes
The general outcomes of interest are OS, change in disease status, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

The existing literature evaluating gastric bypass, SG, BPD, and adjustable gastric banding as a treatment for T2D has varying lengths of follow-up, ranging from 1 to 5 years.

While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. One-year follow-up is necessary to demonstrate weight loss efficacy. Longer follow-up to 5 to 10 years is desirable to assess maintenance of weight loss, impact on co-occurring conditions, and appearance of long-term complications.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

This section focuses on RCTs and systematic reviews of RCTs comparing bariatric surgery with medical therapy.

Review of Evidence
Systematic Reviews
Multiple systematic reviews have evaluated bariatric surgery compared to nonsurgical interventions for individuals with T2DM.[68,69,70,71,72,73,74,]

The most recent systematic review has been conducted by Thomas et al (2023) to assess the clinical efficacy and safety of bariatric surgery compared with medical management in adults with class I obesity and difficult-to-manage T2DM, with or without other comorbidities.[68,]The analysis included 4

RCTs and 8 comparative observational studies, alongside a AHRQ systematic review published in 2023). Of the twelve studies, ten were conducted internationally, while the remaining two, consisting of one RCT and one retrospective cohort study, were conducted in the United States. Of the included studies, 7 assessed RYGB alone (3 RCTs and 4 observational studies), and 3 studies assessed bariatric surgery as a combination of RYGB and sleeve gastrectomy (1 RCT, which also had a small proportion of gastric banding, and 2 observational studies), and 2 studies assessed biliopancreatic diversion with duodenal switch. There were no studies assessing single anastomosis duodeno-ileal bypass with sleeve gastrectomy in this study population.

Complete diabetes remission was reported in 4 RCTs and 6 observational studies. In general, 3 (of 4) RCTs found significantly higher remission rates in those receiving bariatric surgery compared with those receiving various forms of medical management. Remission rates in the studies ranged from 65% at the 6-month follow-up to 38%-42% at the 5-year follow-up for bariatric surgery, compared with 0% at both timepoints in the comparator. The remaining RCT reported a difference in diabetes remission between RYGB and medical management that was not statistically significant (44.5% vs. 24.4%, p =.05). In the observational studies, complete diabetes remission rates ranged from 25% to 100% for bariatric surgery compared with 0% to 3.5% for medical management. Change in BMI from baseline was reported in 4 RCTs and 8 observational studies. Overall, in the RCTs, there were reductions in BMI ranging from −5 to −9 kg/m^2 for bariatric surgery and from −0.8 to −3.4 kg/m^2 for medical management. Notably, reductions in BMI appeared to remain after up to 5 years of follow-up. Similarly, in the observational studies, reductions in BMI ranged from −1 to −8.8 kg/m^2 for bariatric surgery and from 2.4 to −1.8 kg/m^2 for medical management at 1 month to 10 years of follow-up.

The quality of evidence (GRADE) from RCTs and observational studies was assessed as Low to Very Low for both complete diabetes remission and BMI changes across multiple follow-up periods. The investigators reported that bariatric surgery may also reduce the use of medications for type 2 diabetes (GRADE: Low) and may improve quality of life (based on one study) compared with medical management (GRADE: Low). A meta-analysis was not performed due to the clinical and methodological heterogeneity in the patient populations, follow-up periods, definitions of medical management (i.e., the comparator used), and outcome definitions (diabetes remission, medication use). The RCTs involved were limited by their small sample sizes (N ≤ 100) and the potential for bias due to unbalanced attrition among treatment groups. Similarly, the observational cohort studies faced limitations from small sample sizes (with 6 out of 8 studies involving fewer than 100 participants) and risk of bias concerns associated with confounding factors and participant selection, which are inherent challenges in this study design.

Wu et al (2016) published a meta-analysis of studies comparing bariatric surgery with nonsurgical interventions for patients who had T2D.[70,] Eight RCTs with 619 patients were included. RCTs addressed RYGB (6 studies), LAGB (3 studies), LSG (1 study), and BPD (1 study). Mean BMI across studies was 29 kg/m^2 or higher; in 6 of 8 studies, mean BMI was 35 kg/m^2 or higher. One study had a 5-year follow-up, and the others had 1 to 3 years of follow-up. The study with a 5-year follow-up, by Mingrone et al (2015), was limited to patients with a BMI of at least 35 kg/m^2.[75,] All 8 studies reported remission of T2D as an efficacy endpoint. A pooled analysis found a significantly higher rate of T2D remission in the bariatric surgery versus the nonsurgical treatment group (RR, 5.76; 95% CI, 3.15 to 10.55; p<.001). Another diabetes-related outcome (mean reduction in HbA1c levels) was significantly greater after bariatric surgery than nonsurgical treatment (MD, -1.29; 95% CI, -1.70 to -0.87). Also, there was a significantly greater reduction in BMI with bariatric surgery than with nonsurgical treatment (MD, -5.80; 95% CI, -6.95 to -4.64; p<.001). Since the publication of the Wu et al (2016) meta-analysis, 5-year follow-up has been reported for the Schauer et al (2017) RCT, which is shown in Table 18. When the Wu et al (2016) meta-analysis was published, only 3-year findings of the Schauer et al (2017) study were available. The study included patients with T2D who had a BMI of 27 to 43 kg/m^2. The RCTs evaluating bariatric surgery in patients with T2D, including the 5-year follow-up of the Schauer et al (2017) study, are summarized in Table 18.

Yan et al (2016) published a systematic review of RCTs comparing gastric bypass with medical treatment in obese patients (i.e., BMI ≥30 kg/m^2) who had T2D.[69,] The primary study outcome was remission of T2D, which was reported in 5 of the 6 studies. A pooled analysis found a significantly higher remission rate after gastric bypass than after medical treatment (OR, 76.37; 95% CI, 20.70 to 271.73; p<.001). Also, a pooled analysis found a significantly lower final BMI in the gastric bypass group than in the medical treatment group (MD, -6.54 kg/m^2; 95% CI, -9.28 to -3.80 kg/m^2; p<.001).

Muller-Stich et al (2015) published a systematic review of RCTs and observational studies on bariatric surgery in patients with T2D and a BMI less than 35 kg/m^2.[73,] Eleven comparative trials of medical therapy versus bariatric surgery were included, with 5 RCTs and 6 nonrandomized comparative studies identified. Follow-up was between 1 and 3 years. The primary outcome reported was remission of diabetes. On combined analysis, bariatric surgery was associated with a higher remission rate than medical therapy (OR, 14.1; 95% CI, 6.7 to 29.9; p<.001). On secondary outcomes, surgery was associated with a greater decrease in BMI (MD, -5.5 kg/m^2; 95% CI, -6.7 to -4.3; p<.001), a lower HbA1c level (MD, -1.4%; 95% CI, -1.9 to -0.9; p<.001), lower rates of hypertension (OR, 0.25; 95% CI, 0.12 to 0.50; p<.001), and lower rates of dyslipidemia (OR, 0.21; 95% CI, 0.10 to 0.44; p<.001).

Rao et al (2015) published a meta-analysis of short-term outcomes for patients with T2D and a BMI of 35 kg/m^2 or less who underwent RYGB.[74,] Nine articles were included (N=343 patients). After 12 months, patients with T2D had a significant decrease in BMI (weighted MD, -7.42; 95% CI, -8.87 to -5.97; p<.001) and improvements in HbA1c levels (weighted MD, -2.76; 95% CI, -3.41 to -2.11; p<.000). Reviewers reported that longer term follow-up would be needed.

Section Summary: Bariatric Surgery in Adults with Class 1 Obesity and Type 2 Diabetes

Systematic reviews of RCTs and observational studies have found that certain types of bariatric surgery are more efficacious than medical therapy as a treatment for T2D in adults with obesity, including those with a BMI between 30 and 34.9 kg/m^2. The greatest amount of evidence assesses gastric bypass, with some comparative studies on LAGB, LSG, and BPD. Systematic reviews have found significantly greater remission rates of diabetes, decrease in HbA1c levels, and decrease in BMI with bariatric surgery than with nonsurgical treatment. The quality of evidence (GRADE) from RCTs and observational studies was assessed as Low to Very Low for both complete diabetes remission and BMI changes across multiple follow-up periods. The efficacy of surgery is balanced against the short-term risks of the surgical procedure. Most RCTs in this population have 1 to 5 years of follow-up data. Most RCTs in this population have 1 to 5 years of follow-up data.

Bariatric Surgery in Adults With a Body Mass Index Less Than 35 kg/m^2 Who Do Not Have Type 2 Diabetes

Clinical Context and Therapy Purpose

The purpose of any bariatric surgery procedure is to provide a treatment option that is an alternative to or improvement on existing therapies, such as standard medical care, in patients who are not diabetic and a BMI less than 35 kg/m^2.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with a BMI less than 35 kg/m^2 who do not have type 2 diabetes.

Interventions

The therapy being considered is any bariatric surgery procedure.

Comparators

Comparators of interest include standard medical care for nondiabetic patients.

Outcomes
The general outcomes of interest are OS, change in disease status, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

The existing literature evaluating any bariatric surgery procedure has varying lengths of follow-up, ranging from 1 to 3 years. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. One-year follow-up is necessary to demonstrate weight loss efficacy. Longer follow-up to 5 to 10 years is desirable to assess maintenance of weight loss, impact on co-occurring conditions, and appearance of long-term complications.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence
Systematic Reviews
A 2012 TEC Assessment evaluated LAGB in individuals without diabetes who had a BMI less than 35 kg/m^2.[76,] This Assessment was prompted by FDA approval of LAP-BAND for this indication in 2011. The TEC Assessment concluded that LAGB did not meet TEC criteria in these patients and made the following summary statements:

- The evidence on LAGB for patients with lower BMIs is limited both in quantity and quality. There was only 1 small RCT, which had methodologic limitations, a nonrandomized comparative study based on registry data, and several case series. Using the GRADE evaluation, the quality of evidence on the comorbidity outcomes was judged to be low, and the quality of the evidence on the weight loss outcomes was judged to be moderate.
- The evidence was sufficient to determine that weight loss following LAGB was greater than with nonsurgical therapy.
- Direct data on improvement in weight-related comorbidities was lacking. The limited evidence was not sufficient to conclude that the amount of weight loss is large enough that improvements in weight-related comorbidities could be assumed.
- There were very few data on quality of life in this population of patients.
- The frequency and impact of long-term complications following LAGB were uncertain, and this uncertainty has been 1 of the main reasons why it is difficult to determine whether the benefit of LAGB outweighs the risk for this population. While the short-term safety of LAGB has been well-established, the long-term adverse events occur at a higher rate and are less well-defined.

Section Summary: Bariatric Surgery in Adults With a Body Mass Index Less Than 35 kg/m^2 Who Do Not Have Type 2 Diabetes
There is limited evidence for bariatric surgery in patients who are not diabetic and have a BMI less than 35 kg/m^2. A few small RCTs and case series have reported a loss of weight and improvements in comorbidities for this population. However, the evidence does not permit conclusions on the long-term risk-benefit ratio of bariatric surgery in this population.

Bariatric Procedures Other than Open or Laparoscopic Gastric Bypass using a Roux-en-Y, Laparoscopic Adjustable Gastric Banding, Open or Laparoscopic Sleeve Gastrectomy, or Open or Laparoscopic Biliopancreatic Bypass/Diversion with Duodenal Switch

This section briefly summarizes the key evidence on additional bariatric procedures that are used infrequently.

Biliopancreatic Diversion without Duodenal Switch

A TEC Assessment reviewed the available observational studies and concluded that weight loss was similar after BPD without the DS and gastric bypass.[37,] However, BPD without DS leads to complications, especially long-term nutritional and vitamin deficiencies.[77,78,]

Vertical-Banded Gastroplasty

A TEC Assessment identified 8 nonrandomized comparative studies evaluating VBG with gastric bypass.[79,] The Assessment found that weight loss was significantly greater with open gastric bypass than with VBG. Also, VBG has relatively high rates of complications, revisions, and reoperations.

Two-Stage Bariatric Surgery Procedures

The evidence from an RCT[80,] and several case series[81,82,83,] does not support a 2-stage bariatric surgery procedure for improving outcomes in patients with extreme levels of obesity. There is no evidence to suggest that weight loss is improved or that complications are reduced by this approach. Most patients who receive SG as the initial procedure lose sufficient weight during the first year so that a second procedure is no longer indicated. Also, patients undergoing a 2-stage procedure are at risk for complications from both procedures; therefore, it is likely that overall complications are increased by this approach.

Laparoscopic Gastric Plication

There is a shortage of comparative studies, especially RCTs, comparing the safety and efficacy of laparoscopic gastric plication with other bariatric surgery procedures. A 2021 systematic review demonstrated that SG is superior to greater curvature gastric plication with regard to providing effective weight loss through 24 months; statistical significance was not reached at 36 months.[84,] The difference in the improvement of comorbidities and risk of major complications or mortality did not reach statistical significance between groups. One RCT compared endoscopic gastric plication with a sham procedure, reporting 1-year follow-up results in favor of the intervention.[85,] Longer-term follow-up and additional comparative studies are needed.

Single Anastomosis Duodeno-ileal Bypass With Sleeve Gastrectomy

Esparham et al. (2024) conducted a systematic review of 10 studies (N=1707 patients) to examine the mid- and long-term outcomes of SADI-S.[86,] The included studies focused on laparoscopic SADI-S procedures with follow-up periods of ≥ 3 years (ranging from 3 to 10 years). The %EWL ranged from 71% to 89%, with an average of 80% at six and ten years, respectively. The most common late complications observed were malabsorption (6.3%) and GERD (3.6%). Remission rates for hypertension, diabetes, GERD, obstructive sleep apnea, and dyslipidemia varied between 43% and 81%.

In a recent Swedish RCT by Axer et al (2024), the clinical outcomes of SADI-S were compared to those of biliopancreatic diversion with duodenal switch (BPD/DS). Fifty-six patients, with BMI values between 42 and 72 kg/m², were randomly assigned to either the SADI or BPD/DS group.[87,]After one year, both procedures demonstrated similar weight loss outcomes (%EWL: 81.8% ± 13.6% vs. 84.2% ± 14.0%; %TWL: 40.1% ± 5.9% vs. 41.6% ± 6.4%). Early complications occurred in five patients in the SADI group and in four patients in the BPD/DS group with no mortality. Median length of stay was 2 days for both SADI and BPD/DS. Within 30 days, one SADI patient and three BPD/DS patients required re-admission. Serious late complications necessitating reoperation were observed in three SADI and two BPD/DS patients. Additional confirmatory RCTs with larger sample sizes and longer-term follow-up are needed.

Duodenojejunal Sleeve

Chen et al. (2024) performed a systematic review of 30 studies (N=1751) to assess the efficacy and safety of the duodenal-jejunal sleeve for treating obesity and T2DM.[88,] At 12 months post-implantation, there was a reduction in BMI of 4.8 kg/m² (95% CI 4.1, 5.5), an EWL of 41.3% (95% CI 33.4%, 49.2%), and TWL of 13.1% (95% CI 10.1%, 16.0%). Significant reductions in HbA1c and fasting glucose were observed, with standardized mean differences of -0.72 (95% CI -0.95, -0.48) and -0.62 (95% CI -0.82, -0.42), respectively. However, these improvements in weight loss and glycemic control were only partially maintained after explantation. The pooled early removal rate was 19%, and the incidence of severe adverse events was 17%, including device migration (6%), gastrointestinal hemorrhage (4%), device obstruction (4%), and hepatic abscess (2%). Further research is needed to better understand the long-term efficacy and safety of this procedure, including its associated risks. A prior meta-analysis of 5 RCTs found significantly greater short-term weight loss (12 to 24 weeks) with the use of duodenojejunal sleeve compared to medical therapy.[89,] However, no significant differences in diabetes-related symptom reduction were observed between groups. All included RCTs featured small sample sizes and were deemed by the investigators to be at high risk of bias.

Intragastric Balloon Devices

Evidence includes RCTs,[90,91,] a case series with long-term follow-up on 1 of the devices,[92,] and systematic reviews on various intragastric balloon (IGB) devices.[93,94,95,96,] RCTs have found significantly better weight loss outcomes with IGB devices compared with sham treatment or LT alone. One RCT followed patients for an additional 6 months after IGB removal and found sustained weight loss. A large case series with follow-up up to 5 years has suggested that patients regain weight over time. Additional long-term follow-up data are needed. There are some adverse events, and in a minority of cases, these adverse events can be severe. The FDA wrote 2 letters in 2017 to health care providers, 1 warning of spontaneous balloon inflation and pancreatitis and the other reporting 5 unanticipated deaths occurring in 2016 to 2017 following the IGB procedure. In June 2018, the FDA reported that, since 2016, a total of 12 deaths occurred in patients with liquid-filled intragastric balloons worldwide; 7 of these deaths were in patients in the U.S. Health care providers are encouraged to monitor patients receiving IGBs.

Aspiration Therapy Device

The evidence consists of an RCT with 4 years of follow-up[97,] and a small case series with up to 2 years of follow-up.[98,] The RCT found significantly greater weight loss (measured several ways) with AT compared with LT at 1 year. Forty of 58 patients (69%) achieved at least 10% TWL at 4 years or at time of study withdrawal; however, only 15/111 initial AT patients completed the study through 4 years. In addition to a high degree of missing data, the PATHWAY study noted a potentially high degree of adverse events related to A-tube malfunction, an element of the therapy which is expected to require replacement within approximately 3.5 years postgastrostomy in 50% of cases. The impact of this on health outcomes compared to existing surgical approaches is unknown. The case series followed only 15 patients more than 1 year; at 2 years, study completers had not regained weight and instead had lost additional excess weight. The total amount of data on AT remains limited and additional studies need to be conducted before conclusions can be drawn about the long-term effects of treatment on weight loss, metabolism, safety, and nutrition.

Bariatric surgeries performed in 2 stages have been proposed as a treatment option, particularly for patients with "super-obesity" defined as a BMI greater than 50 kg/m^2. The rationale for a 2-stage procedure is that the risk of an extensive surgery is prohibitive in patients who are extremely obese. Therefore, a procedure with low-risk (usually an SG) is performed first. After the patient loses some weight, thus lowering the surgical risk, a second more extensive procedure (e.g., BPD) is performed.

Revision Bariatric Surgery

Clinical Context and Therapy Purpose

The purpose of revision bariatric surgery is to address complications of a procedure or a procedure that has failed. Severe GERD is one of the most common indications for revision surgery.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals who have had bariatric surgery.

Interventions
The therapy being considered is revision bariatric surgery to address perioperative or late complications of a bariatric procedure, to address bariatric surgery that has failed due to dilation of the gastric pouch or dilation proximal to an adjustable gastric band, or to address severe GERD refractory to medical treatment.

Comparators
Comparators of interest include standard medical care without revision surgery.

Outcomes
The general outcomes of interest are OS, change in disease status, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

The existing literature evaluating revision bariatric surgery has varying lengths of follow-up, ranging from 1 to 3 years. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. One-year follow-up is necessary to demonstrate weight loss efficacy. Longer follow-up of 5 to 10 years is desirable to assess maintenance of weight loss, impact on co-occurring conditions, and appearance of long-term complications.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence
Systematic Reviews
Ataya et al (2023) published a systematic review and meta-analysis of 817 patients (n=7 retrospective comparative studies) to assess the outcomes of revisional procedures, namely RYGB (413 patients) and one anastomosis gastric bypass (OAGB, 404 patients) following unsuccessful SG.[99,]OAGB resulted in greater weight loss than RYGB, with a mean difference of -5.84 (95% CI, -6.74 to -4.94; p<.00001; I^2=0%), greater total weight loss, and a higher diabetes remission rate (OR, 0.32; 95% CI, 0.14 to 0.71). However, OAGB was associated with a significantly higher incidence of postoperative GERD than RYGB (52 vs. 31: OR, 0.40; 95% CI, 0.24 to 0.67; p=.0005; I^2=0%).

Matar et al (2021) published a systematic review of 556 patients (n=17 studies) who underwent RYGB for SG-related complications, including GERD (30.4% cases) and insufficient weight loss and weight regain (52% of cases).[100,] The mean BMI at the time of conversion ranged from 33.3 to 48.3 kg/m^2. The pooled baseline BMI at conversion was 38.5 kg/m^2 (95% CI, 36.49 to 40.6), at 6 months was down to 28.6 kg/m^2 (95% CI, 16.1 to 41.0), and after 1 year was up to 32.1 kg/m^2 (95% CI, 25.50 to 38.7). The pooled mean %TWL after completion of treatment was 25.2% (95% CI, 12.8 to 37.5) at 6 months and 22.8% (95% CI, 13.5 to 32.1) at 1 year. There was a 16.4% complication rate at 30 days, which decreased

to 11.4% after 30 days. At 1-year post RYGB, the rate of resolution for common comorbidities was as follows: GERD, 79.7% (95% CI, 59.6 to 91.3); T2D, 57.7% (95% CI, 36.9 to 76.1); and hypertension, 49.4% (95% CI, 25.8 to 73.3).

Parmar et al (2020) published a systematic review of 1075 patients (n=17 studies) who underwent one OABG as a revisional bariatric procedure after failure of a primary LAGB and SG.[101,] No RCTs were available on this topic and no meta-analyses were performed as part of this systematic review. The most commonly reported reason for revisional surgery was poor response (81%) followed by gastric band failure (35.9%), GERD (13.9%), intolerance (12.8%), staple line disruption (16.5%), pouch dilatation (17.9%), and stomal stenosis (10.3%). Results revealed that after the revisional OABG , the mean percent EWL was 50.8% at 6 months, 65.2% at 1 year, 68.5% at 2 years, and 71.6% at 5 years. Resolution of comorbidities after OAGB- was significant with 80.5% of patients with T2D, 63.7% of patients with hypertension, and 79.4% of patients with reporting resolution. The overall readmission rate following OAGB was 4.73%, the mortality rate was 0.3%, and the leak rate was 1.54%. Although the authors concluded that OAGB is a safe and effective choice for revisional bariatric surgery, RCTs on this topic are needed as currently only retrospective cohort studies with heterogenous data are available.

Brethauer et al (2014) conducted a systematic review of reoperations after primary bariatric surgery for the American Society for Metabolic and Bariatric Surgery that included 175 studies, most of which were single-center retrospective reviews.[102,] The review is primarily descriptive, but made the following conclusions: "The current evidence regarding reoperative bariatric surgery includes a diverse group of patient populations and procedures. The majority of the studies are single institution case series reporting short- and medium-term outcomes after reoperative procedures. The reported outcomes after reoperative bariatric surgery are generally favorable and demonstrate that additional weight loss and co-morbidity reduction is achieved with additional therapy. The risks of reoperative bariatric surgery are higher than with primary bariatric surgery and the evidence highlights the need for careful patient selection and surgeon expertise."

Nonrandomized Studies

A retrospective study reported by Dang et al (2023) analyzed serious complications and mortality in patients who underwent revision surgery (conversion of SG to RYGB, N= 13,432) or primary RYGB (N=84,543) in 2020 and 2021.[103,] GERD was the most common indication for revision (55.3%), followed by weight regain (24.4%), and inadequate weight loss (12.7%). Revisional RYGB after SG was associated with a higher rate of serious complications than primary RYGB (7.2% vs. 5.0%, p<.001). There was no significant difference in 30-day mortality.

Petrucciani et al (2021) published a retrospective analysis of 215 patients who underwent revisional OAGB with a biliopancreatic limb of 150 cm after failing LAGB at a single center between 2010 and 2016.[104,] The indication for surgery was weight loss failure in 30.7% of cases and long-term complications in the remaining cases. The mean BMI at the time of OAGB was 42 kg/m^2. At 2 years after OAGB, 9.7% of patients were lost to follow-up, BMI was down to 28 ± 5.5 kg/m^2, %EWL was 88.2 ± 23.9, and %TWL was 38.7 ± 9.3. At 5 years after OAGB, 16.6% of patients were lost to follow-up, BMI was slightly up to 29.2 ± 5.8 kg/m^2, %EWL was 82.4 ± 25, and %TWL was 36.1 ± 10. Overall postoperative morbidity was 13.5% with a 5.9% rate of postoperative abscess with or without staple line leak. Treatment-resistant occurred in 21.3% of patients; conversion to RYGB was required in 4.2% of cases.

Sudan et al (2015) reported on safety and efficacy outcomes for reoperative bariatric surgeries using data from a national registry, the Bariatric Outcomes Longitudinal Database.[105,] The Bariatric Outcomes Longitudinal Database was a large, multi-institutional bariatric surgery–specific database to which data were submitted from 2007 through 2012 by 1029 surgeons and 709 hospitals participating in the Bariatric Surgery Centers of Excellence program. Surgeries were classified as primary or reoperative bariatric. Reoperations were further divided into corrective surgeries (when

complications or incomplete treatment effect of a previous bariatric operation was addressed, but the initial operation was not changed) or conversions (when an index bariatric operation was changed to a different type of bariatric operation or a reversal restored original anatomy). Of 449,473 bariatric operations in the database, 420,753 (93.6%) operations had no further reoperations (primary operations) while 28,270 (6.3%) underwent reoperations. Of the reoperations, 19,970 (69.5%) were corrective and 8750 (30.5%) were conversions. The primary bariatric operations were RYGB (n=204,705 [49.1%]), LAGB (n=153,142 [36.5%]), SG (n=42,178 [10%]), and BPD-DS (n=4260 [1%]), with the rest classified as miscellaneous. LAGB was the most common primary surgery among conversions (57.5% of conversions; most often [63.5%] to RYGB). Compared with primary operations, mean hospital length of stay was longer for corrections (2.04 days vs. 1.8 days, p<.001) and for conversions (2.86 days vs. 1.8 days, p<.001). Mean percent EWL at 1 year was 43.5% after primary operation, 39.3% after conversions, and 35.9% after corrective operations (statistical comparison not reported). One-year mortality was higher for conversions (0.31%) than for primary surgeries (0.17%; p<.001), with no statistically significant difference for corrections (0.24%) compared with primary surgeries (0.17%; p=not significant [NS]). One-year serious adverse event rates were higher for conversions (3.61%) than for primary operations (1.87%; p<.001), with no statistically significant difference for corrections (1.9%) compared with primary operations (1.87%; p=NS). The authors concluded that reoperation after primary bariatric surgery is relatively uncommon, but generally safe and efficacious when it occurs.

Endoscopic Revision Procedures

While bariatric surgery revision or correction can be conducted using standard surgical approaches, novel endoscopic procedures are being developed. Some procedures use devices also being evaluated for the endoscopic treatment of GERD (see evidence review 2.01.38). The published data on the use of these devices for treatment of regained weight is limited. Published case series have reported results using a number of devices and procedures (including sclerosing injections) as a treatment for this condition. The largest series (2007) found involved 28 patients treated with a sclerosing agent (sodium morrhuate).[106,] Reported trials that used 1 of the suturing devices had fewer than 10 patients. For example, Herron et al (2008) reported on a feasibility study in animals.[107,] Thompson et al (2006) reported on a pilot study with changes in anastomotic diameter and weight loss in 8 patients who regained weight and had dilated gastrojejunal anastomoses after RYGB.[108,] No comparative trials were identified; comparative trials are important because of the known association between an intervention and short-term weight loss.

The StomaphyX device, which has been used in this approach, was cleared by FDA through the 510(k) process. It was determined to be equivalent to the EndoCinch system, which has 510(k) marketing clearance for endoscopic suturing for gastrointestinal tract surgery. Eid et al (2014) reported on results from a single-center RCT that compared the StomaphyX device with a sham procedure for revisions in patients with prior weight loss after RYGB at least 2 years earlier.[109,] Enrollment was initially planned for 120 patients, but the trial was stopped prematurely after 1-year follow-up was completed by 45 patients in the StomaphyX group and 29 patients in the sham control group because preliminary analysis failed to achieve the primary efficacy endpoint in at least 50% of StomaphyX patients. The primary 12-month efficacy endpoint (reduction in pre-RYGB excess weight by ≥15%, excess BMI loss, and BMI <35 kg/m^2) was achieved by 10 (22.2%) of 45 in the StomaphyX group and 1 (3.4%) of 29 in the sham control group (p<.01).

A 2009 survey of American Society for Metabolic and Bariatric Surgery members (bariatric surgeons) indicated different risk tolerance and weight loss expectations for primary and revisional endoscopic procedures.[57,] The surgeons were "willing to accept less weight loss and more risk for revisional endoluminal procedures than for primary endoluminal procedures." The durability of the procedures was a concern, and most surgeons were unwilling to consider the procedures until their efficacy has been proven. A 2013 systematic review of studies reporting outcomes after endoluminal revision of primary bariatric surgery conducted by the American Society for Metabolic and Bariatric Surgery concluded: "The literature review shows the procedures on the whole to be well tolerated with limited

efficacy. The majority of the literature is limited to small case series. Most of the reviewed devices are no longer commercially available."[110,]

Cohen et al (2019) conducted a systematic review evaluating the safety and efficacy of endoscopic gastroplasty for medically uncontrolled obesity.[111,] Nine observational studies and a single RCT were identified by the authors. Follow-up duration in the majority of studies was limited to 6 to 12 months with several studies reporting high rates of loss to follow-up. Percent total body weight loss ranged from -15.1% to 19.5%. Reduction in BMI ranged from -1.69 to -7.5 kg/m^2. Serious adverse events ranged from 2% to 10%. The quality of the current evidence was graded very low to moderate, with limited long-term data on weight loss durability and procedure safety.

Section Summary: Revision Bariatric Surgery

Systematic reviews and case series have shown that patients receiving revision bariatric surgery experienced satisfactory weight loss and reduced comorbidities including GERD. Data from a multinational bariatric surgery database has found that corrective procedures following primary bariatric surgery are relatively uncommon but generally safe and efficacious. A large retrospective analysis found a serious complication rate of 7.2% for conversion to RYGB in 13,432 individuals and no difference in 30-day mortality compared to primary RYGB.

Bariatric Surgery in Adolescents

Clinical Context and Therapy Purpose

The purpose of bariatric surgery is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as standard medical care, in individuals who are adolescents with obesity.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals who are adolescents with obesity. While guidelines for bariatric surgery in adolescents are not uniform, most use weight-based criteria that parallel those for adults.

Interventions

The therapy being considered is open or laparoscopic gastric bypass, laparoscopic adjustable gastric banding, or open or laparoscopic sleeve gastrectomy.

Comparators

Comparators of interest include standard medical care. Treatment for adolescent children with obesity includes physical exercise, low carbohydrate dieting, and low-fat dieting.

Outcomes

The general outcomes of interest are OS, change in disease status, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

The existing literature evaluating gastric bypass, LAGB, or SG as a treatment for obesity has varying lengths of follow-up, ranging from 1 to 6 years. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. One-year follow-up is necessary to demonstrate weight loss efficacy. Longer follow-up to 5 to 10 years is desirable to assess maintenance of weight loss, impact on co-occurring conditions, and appearance of long-term complications.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Bariatric Surgery Techniques in Adolescents
Review of Evidence

Systematic Reviews

Oei et al. (2024) conducted a systematic review and meta-analysis on bariatric surgery for managing pediatric obesity, focusing on patient-reported outcome measures, cardiometabolic risk factors, anthropometry, and adverse events (AEs) (Table 7).[112,]This review was undertaken in support of the Canadian Clinical Practice Guideline for Managing Pediatric Obesity. The review included studies through January 2022, comprising RCTs and observational studies with reported baseline ages from 10 to 21 years old (mean <18 years old) and participants with baseline BMI values from 38.5 to 66.2 kg/m^2. Of the 63 eligible publications, 43 were original studies (N=6128 participants, 66% female). Six surgical techniques were evaluated, mostly through uncontrolled observational studies. Short-term follow-up (<18 months) was common. Surgery significantly improved health-related quality of life, cardiometabolic risk factors, and body mass index Z-score (BMIz) compared to baseline. Mild or non-specific AEs were reported, with serious AEs being rare.

Qi et al (2017) published a systematic review and meta-analysis on the use of bariatric surgery for the treatment of adolescents with obesity (Table 7).[113,] In a literature search conducted through July 2017, 49 studies were identified for inclusion. Study quality was assessed using the Newcastle-Ottawa Scale. Age of patients ranged from 14 to 20 years. BMI ranged from 34 to 63 kg/m^2. Overall results showed significant improvements in BMI as well as glycemic and lipid control with various bariatric surgery techniques. RYGP showed the largest improvements compared with other procedures, with LAGB and SG also showing improvements in this population.

In a systematic review of 23 studies, Black et al (2013) concluded that the available literature demonstrated a high rate of significant short-term weight loss after bariatric surgery (Table 7).[114,] The literature search was conducted through January 2013. Quality assessment of the included studies was not discussed. Ages of patients at the time of surgery ranged from 5 to 23 years. A meta-analysis showed significant reductions in BMI. Meta-analyses were not conducted on the resolution of comorbidities due to heterogeneity in reporting. However, most cases of hypertension, OSA, T2D, and dyslipidemia were reported to have resolved at 1-year follow-up. Reviewers noted that complication and comorbidity rates were not well-defined.

Treadwell et al (2008) conducted a systematic review and meta-analysis of the published evidence on bariatric surgery in adolescents (Table 7).[115,] Their analysis included English-language articles on currently performed procedures when data were separated by procedure, and there was a minimum 1-year follow-up for weight and BMI. Studies must have reported outcomes data for 3 or more patients ages 21 years or younger, representing at least 50% of pediatric patients enrolled at that center. Nineteen studies reported on between 11 and 68 patients who were 21 years or younger. Eight studies of LAGB (mean BMI, 45.8 kg/m^2; median age range, 15.6 to 20 years); 6 studies on RYGB (mean BMI, 51.8 kg/m^2; median age range, 16 to 17.6 years); 5 studies of other procedures (mean BMI, 48.8 kg/m^2; median age range, 15.7 to 21 years) were included.

Meta-analyses of BMI at longest follow-up indicated sustained and clinically significant reductions for both LAGB and RYGB (Table 8). Comorbidity resolution was sparsely reported, but surgery appeared to resolve some medical conditions, including diabetes and hypertension; 2 studies of LAGB showed large rates of diabetes resolution but low patient enrollment, and only 1 study of RYGB reported relevant data. No in-hospital or postoperative deaths were reported in any LAGB study. The most frequently reported complications for LAGB were band slippage and micronutrient deficiency with sporadic cases of band erosion, port/tube dysfunction, hiatal hernia, wound infection, and pouch dilation. More severe complications were reported for RYGB, such as pulmonary embolism, shock, intestinal obstruction, postoperative bleeding, staple line leak, and severe malnutrition. No in-hospital deaths were reported; however, 1 patient died 9 months after the study with severe *Clostridium difficile* colitis; 3 others died of causes not likely to have been directly related to the bariatric surgeries. No LAGB studies reported data on the impact of surgery on growth and development. One study of RYGB reported pre- and postoperative heights and concluded that there was no evidence of growth retardation at an average follow-up of 6 years, but it could not be determined from the data whether expected growth was achieved.

Table 7. Systematic Review Characteristics for Bariatric Surgery for Adolescents With Obesity

Study	Dates	Studies	Participants	Design	Duration
Oei et al (2024)[112,]	Jan 2022	63	6128	1 RCT 13 controlled 49 uncontrolled	short (<18 months); intermediate (18–24 months); long-term (>24 months)
Qi et al (2017)[113,]	Jul 2017	49	RYGP: 1216 LAGB: 1028 LSG: 665 Other: 98	1 RCT 22 prospective 26 retrospective	12 to 120 mo
Black et al (2013)[114,]	Jan 2013	23	RYGP: 256 LAGB: 271 LSG: 90 Other: 20	1 controlled 22 uncontrolled	6 to 120 mo
Treadwell et al (2008)[115,]	Dec 2007	18	RYGB: 131 LAGB: 352 Other: 158	1 prospective 17 retrospective	0 to 22 y

LAGB: laparoscopic adjustable gastric banding; LSG: laparoscopic sleeve gastrectomy; RCT: randomized controlled trial; RYGP: Roux-en-Y gastric bypass.

Table 8. Systematic Review Results for Bariatric Surgery for Adolescents With Obesity

Study	BMI Reduction Mean Difference (95% CI)	Fasting Blood Insulin, mIU/L Mean Difference (95% CI)	Total Cholesterol, mg/dL Mean Difference (95% CI)
Oei et al (2024)[112,]			
RYGP	-11.2 (-13.3 to -9.1)	-106.9 (-118.1 to -95.7)	NR
LAGB	-6.4 (-8.1 to -4.6)	-86.5 (-101.8 to -72.3)	-0.1 (-0.2 to 0.1)
LSG	-12.2 (-13.7 to -10.7)	-87.5 (-106.9 to -68.2)	-0.2 (-0.4 to -0.1)
Mixed	-7.0 (-9.3 to -4.7)	-73.3 (-97.7 to -47.8)	-0.1 (-0.3 to 0.1)
Qi et al (2017)[113,]			
RYGP	18.5 (16.4 to 20.7)	24.8 (10.0 to 30.7)	29.4 (18.1 to 40.7)
LAGB	12.1 (11.0 to 13.3)	20.5 (16.4 to 24.6)	2.2 (-10.0 to 14.4)

Study	BMI Reduction Mean Difference (95% CI)	Fasting Blood Insulin, mIU/L Mean Difference (95% CI)	Total Cholesterol, mg/dL Mean Difference (95% CI)
LSG	16.0 (13.2 to 20.7)	18.4 (11.4 to 25.3)	13.6 (2.9 to 24.2)
Other	23.2 (15.6 to 30.7)	28.3 (5.7 to 50.9)	49.5 (29.9 to 69.2)
Black et al (2013)[114,]			
RYGP	17.2 (14.3 to 20.1)	NR	NR
LAGB	10.5 (9.1 to 11.8)	NR	NR
LSG	14.5 (11.7 to 17.3)	NR	NR
Other	NR	NR	NR
Treadwell et al (2008)[115,]			
RYGP	(17.8 to 22.3)	NR	NR
LAGB	(10.6 to 13.7)		

BMI: body mass index; CI: confidence interval; LAGB: laparoscopic adjustable gastric banding; LSG: laparoscopic sleeve gastrectomy; NR: not reported; RYGP: Roux-en-Y gastric bypass.
[a] Short-term FU (<18 months); [b] Intermediate FU (18-24 months); [c] Long-term FU (>24 months); [d] Measured as pmol/L; [e] Measured as mmol/L; [f] No point estimate provided; only 95% CIs given.

Randomized Controlled Trials

Roebroek et al (2024) conducted a single-center RCT designed to assess one-year health effects of bariatric surgery in 59 adolescents aged 14 to 16 years with severe obesity (BMI ≥40 kg/m^2, or ≥35 kg/m^2 in combination with comorbidity).[116,]Participants were assigned to multidisciplinary lifestyle intervention (MLI) combined with LAGB (n=29) versus only MLI (n=30). Main outcomes were weight change and sex- and age-specific BMI loss. Additionally, glucose metabolism, blood pressure and lipid profile were analyzed. Mean (±SD) weight loss in the surgery group was 11.2 ± 7.8% after 12 months, compared to a weight gain of 1.7 ± 8.1% in the control group. The fasting insulin, insulin resistance score and lipid profile improved significantly in the surgery group. There is a need to further assess the evidence on safety and long-term efficacy of LAGB in this study population.

Section Summary: Bariatric Surgery Adolescents

Gastric Bypass, Laparoscopic Adjustable Gastric Banding, or Sleeve Gastrectomy

Several systematic reviews and meta-analyses on bariatric surgery for adolescents with obesity found overlaps among studies, primarily assessing gastric bypass, SG, and LAGB. A recent meta-analysis indicated improved health-related quality of life, cardiometabolic risk factors, and BMI. An RCT reported significant weight loss and metabolic improvements with LAGB compared to conservative treatment. Adolescent outcomes in percent EWL and BMI change are similar to adults, though concerns about developmental maturity, psychosocial status, and informed consent are greater.

Bariatric Surgery Other Than Gastric Bypass, Laparoscopic Adjustable Gastric Banding, or Sleeve Gastrectomy

There is less evidence for the use of bariatric techniques other than gastric bypass, LAGB, and SG. Sample sizes are small for these other techniques and meta-analyses have shown wide CIs in the estimates.

Guideline recommendations for bariatric surgery in adolescents lack uniformity but generally correspond to the clinical selection criteria for adults and supplement these clinical selection criteria with greater attention to issues of maturity and psychosocial status.

Bariatric Surgery in Preadolescent Children
Review of Evidence

Systematic Reviews
Black et al (2013; described above) published a systematic review of 23 studies on bariatric surgery in children and adolescents.[114,]

Shah et al. (2024) conducted an analysis of surgical outcomes in preteens versus teens using data from the American College of Surgeons-Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program database.[117,]Among the 4755 patients identified, 47 were <13 years old. The study found that preteens had a similar BMI (46.9 ± 7 vs. 47 ± 13 kg/m2) to their teenage counterparts. Preteens were more prone to sleep apnea and TD2M. Notably, preteens experienced no complications compared to teens and had no unplanned readmissions (0% vs. 2.9%) or reoperations (0% vs. 0.8%) within 30 days post-surgery. Furthermore, there were no mortalities among preteens (0% vs. 0.1%). The risk-adjusted decrease in BMI between preteens and teens was similar at the 30-day mark (4.2 [95% CI: 3.0 to 5.4] vs. 4.6 [95% CI: 4.4 to 4.7], p=.6). For preteens, the decrease in BMI was 7 ± 3 kg/m^2 at 3 months and 9 ± 4 kg/m^2 at 12 months post-surgery, translating to a percentage BMI change of 16 ± 7 and 20 ± 8, respectively.

Nonrandomized Studies
Alqahtani et al (2021), described above, included children as young as 5 years of age in their prospective, noncomparative cohort study analyzing durability of weight loss and comorbidity resolution, growth velocity, and adverse events associated with LSG in children and adolescents with severe obesity over 10 years.[118,] In the 5- to 14-year age group, 801 (32%) children were included. The mean percent of 95th percentile at baseline for children in this age group was 177% ± 38%. The %EWL after LSG in children aged 5 to 14 years was not significantly different from the adolescent children (>14 years) as results were consistent across age groups. Additionally, the height z-score change did not differ in this age group, indicating no impact on change over 10 years of follow-up.

Section Summary: Bariatric Surgery in Preadolescent Children
There is a scarcity of published data, and no studies have been identified that specifically focus on bariatric surgery in preadolescent children. However, a recent prospective noncomparative cohort study by Alqahtani et al. (2021) has shown significant, long-term (follow-up of 10 years) weight loss and resolution of comorbidities without safety concerns following LSG in children as young as 5 years old (32% of children were between the ages of 5 and 14 at the time of surgery). Additionally, a recent analysis of surgical outcomes in preteens versus teens, using data from the American College of Surgeons-Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program database, demonstrated that bariatric surgery in preteens is both safe and effective when performed at specialized centers. Nonetheless, further comparative studies are required to draw definitive conclusions about the net health benefits of bariatric surgery in preadolescent children with obesity.

Hiatal Hernia Repair in Conjunction With Bariatric Surgery for Adults with Class 3 Obesity and a Preoperative Diagnosis of Hiatal Hernia

Clinical Context and Therapy Purpose
The purpose of hiatal hernia repair with bariatric surgery is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as standard medical care, in patients with class 3 obesity and a preoperative diagnosis of hiatal hernia.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with class 3 obesity and a preoperative diagnosis of hiatal hernia.

Interventions
The therapy being considered is hiatal hernia repair with bariatric surgery.

Comparators
Comparators of interest include standard medical care. Treatment for patients with class 3 obesity and a preoperative diagnosis of hiatal hernia includes physical exercise, low carbohydrate dieting, and low-fat dieting.

Outcomes
The general outcomes of interest are OS, change in disease status, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

The existing literature evaluating hiatal hernia repair with bariatric surgery as a treatment for class 3 obesity and a preoperative diagnosis of hiatal hernia has varying lengths of follow-up, ranging from 1 to 3 years. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. One-year follow-up is necessary to demonstrate weight loss efficacy. Longer follow-up to 5 to 10 years is desirable to assess maintenance of weight loss, impact on co-occurring conditions, and appearance of long-term complications.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence
Hiatal hernia is associated with obesity, and existing hiatal hernias may be worsened with bariatric surgery. In some studies, the presence of a hiatal hernia has been associated with complications after LAGB.[119,] Although other studies have reported no differences in perioperative complications after LAGB in patients with and/or a hiatal hernia or those without and/or hiatal hernia.[120,] Hiatal hernias, either incidentally found at surgery or diagnosed preoperatively, are often repaired at the time of bariatric surgery. In 2013, the Society of American Gastrointestinal and Endoscopic Surgeons published guidelines on the management of hiatal hernia, recommending that, during RYGB, SG, and the placement of LAGBs, all detected hiatal hernias should be repaired (grade of recommendation: weak; evidence quality moderate).[121,] There is limited evidence regarding whether repair of hiatal hernias at the time of bariatric surgery improves outcomes after surgery; it consists primarily of cohort studies comparing outcomes for patients who had a hiatal hernia and underwent repair during bariatric surgery with patients without a hiatal hernia.

Systematic Reviews
Chen et al (2021) published a systematic review of 18 studies that evaluated outcomes after hiatal hernia repair plus SG in obese patients (N=937).[122,] Results demonstrated that patients who underwent hiatal hernia repair during SG (concomitant approach) had significant reductions in BMI

(MD, -11.42 kg/m^2, 95% CI, -12.8 to -10.03), and the risk of symptoms (OR, 0.20; 95% CI, 0.10 to 0.41) and esophagitis (OR, 0.12; 95% CI, 0.05 to 0.26). Hiatal hernia repair during SG was superior to SG alone for remission (OR, 2.97; 95% CI, 1.78 to 4.95), but not de novo (OR, 0.61; 95% CI, 0.24 to 1.53). The pooled recurrence rate for hiatal hernia after hiatal hernia repair plus SG was 11% (95% CI, 4 to 19). Malaussena et al (2024) conducted a meta-analysis of 27 studies to determine the optimal surgical approach for bariatric patients with hernias.[123,]The study evaluated three options for ventral hernia repair in these patients: a staged approach where bariatric surgery precedes definitive hernia repair (BS-first), a staged approach where hernia repair precedes bariatric surgery (HR-first), or a concomitant approach. Seven comparative studies were included, with 8548 staged patients (6458 BS-first) and 3528 concomitant patients. Additionally, 7 single-arm staged studies and 13 single-arm concomitant studies were analyzed. The concomitant approach was found to reduce the odds of surgical site infections, reoperation, and seromas. Conversely, the staged approach (BS-first) was associated with a lower risk of mesh infection. The single-arm studies indicated that hernia recurrence was less frequent with the staged BS-first approach compared to the concomitant approach. These findings suggest that a concomitant approach is suitable for hernias not requiring mesh, whereas the staged (BS-first) approach is preferable for hernias requiring mesh placement.

Section Summary: Hiatal Hernia Repair in Conjunction With Bariatric Surgery for Adults with Obesity and a Preoperative Diagnosis of Hiatal Hernia

Hiatal hernia repair is frequently undertaken at the time of bariatric surgery. The evidence related to whether hiatal hernia repair improves outcomes after bariatric surgery is limited, particularly for hiatal hernias that are incidentally diagnosed at the time of surgery. For patients with a preoperative diagnosis of a hiatal hernia, symptoms related to a hernia, and indications for surgical repair, it is reasonable to undertake this procedure at the time of bariatric surgery. For other patients, it is uncertain whether repair of a hiatal hernia at the time of bariatric surgery improves outcomes. A systematic review found that hiatal hernia repair during SG was superior to SG alone for remission, but not de novo. This combined approach of hernia repair during bariatric surgery has also been shown in a meta-analysis to significantly lower the risk of surgical site infections, reoperations, and seromas.

Esophagogastroduodenoscopy with Bariatric Surgery

Clinical Context and Test Purpose

Esophagogastroduodenoscopy (EGD) has been proposed to serve several roles in bariatric surgery, serving functions across preoperative, intraoperative, and postoperative stages. Before the surgery, EGD is employed to detect any preexisting gastrointestinal conditions that might influence the surgical approach or require plan adjustments. During the operation, EGD assists the surgeon in positioning instruments accurately and identifying any immediate complications. After the surgery, EGD is used for monitoring the healing process, identifying complications such as leaks or strictures, and addressing any new symptoms or concerns.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals undergoing a EGD either prior to, during or after bariatric surgery of any form.

Interventions

The therapy being considered is EGD before, during, and after bariatric surgery.

Comparators

Comparators of interest may include other diagnostic procedures used to evaluate the gastrointestinal tract. These can include imaging studies such as upper gastrointestinal series, CT scans, and MRI. Additionally, other endoscopic techniques like capsule endoscopy and endoscopic ultrasound may be considered when assessing the structure and function of the esophagus, stomach,

and duodenum. Each of these alternatives has specific indications and limitations, and the choice of procedure will depend on the patient's specific medical condition and the surgeon's assessment.

Outcomes

The general outcomes of interest are overall survival, change in disease status, health status measures, surgical outcomes, functional outcomes, quality of life, and test validity.

Before the surgery, EGD is employed to detect any preexisting gastrointestinal conditions that might influence the surgical approach or require plan adjustments.

- Clinical validity: EGD accuracy in detecting preexisting conditions that influence surgical decisions
- Clinical utility: Surgical outcomes (immediate and delayed); quality of life

During the operation, EGD assists the surgeon in positioning instruments accurately and identifying any immediate complications.

- Clinical validity: EGD accuracy in assisting in positioning and identifying complications
- Clinical utility: Surgical outcomes (immediate and delayed); quality of life

After the surgery, EGD is used for monitoring the healing process, identifying complications such as leaks or strictures, and addressing any new symptoms or concerns.

- Clinical validity: EGD accuracy in detecting delays in healing, complications and new symptoms
- Clinical utility: Surgical outcomes (long term); functional outcomes; quality of life

Study Selection Criteria

For the evaluation of the clinical validity of the tests included in this review, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology
- Included a suitable reference standard. The standard for evaluation is clinical assessment. The decision to conduct an EGD is made at the surgeon's discretion. For instance, the ASMBS advises that the use of EGD should be selective and based on the presence of relevant symptoms.
- Patient/sample clinical characteristics were described
- Patient/sample selection criteria were described.

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse). Please see above outcomes section.

Review of Evidence

Muir et al. (2023) conducted the most comprehensive systematic review and meta-analysis to date, incorporating 47 observational studies and assessing a total of 23,368 patients.[124,] Notably, 20% of these patients had findings from EGD that either altered their operative management or postponed their bariatric surgery. Although the heterogeneous nature of the reporting in the included studies precluded a meta-analysis of the specific causes for these findings, the most frequently reported conditions were gastritis, hiatus hernia, and esophagitis. The remaining 80% of patients who underwent preoperative EGD saw no changes to their surgical plans or delays in their surgery due to the procedure. Similar results have been reported in previous systematic reviews regarding the proportions of patients in whom EGD did not impact management.[125,] There is a need for direct, comparative, homogenous studies assessing whether EGD should be routine before bariatric surgery, and whether it is judicious to expose many patients to an invasive procedure that has potential risk and insufficient evidence of effectiveness.

The ASMBS (2021) conducted a literature review on the significance of preoperative EGD for patients considering bariatric surgery.[126,] This review aimed to support the ASMBS's position statement on the

necessity of upper gastrointestinal endoscopy both before and after bariatric surgery (see Practice Guidelines and Position Statements section). The review identified 28 studies that assessed the role of endoscopy in patients, whether symptomatic or asymptomatic, before undergoing bariatric surgery. These studies collectively included 12,385 patients, with an average age of 44 years, 68% of whom were female, and an average BMI of 45.9 kg/m² (ranging from 40.6 to 50.1 kg/m²). The analysis revealed that 27% of all patients seeking bariatric surgery were diagnosed with GERD. Among patients, regardless of gastrointestinal symptoms, the prevalence of hiatal hernia, erosive esophagitis, and Barrett's esophagus was 21%, 16%, and 3%, respectively. Furthermore, 35% of patients had at least one abnormal finding during endoscopy. Notably, among those seeking bariatric surgery without any gastrointestinal or GERD symptoms, the detection rates for hiatal hernia, erosive esophagitis, and Barrett's esophagus were 17%, 17%, and 1%, respectively.

Clinical Utility

Evidence supporting the clinical utility of EGD in bariatric surgery is limited. Current research primarily addresses the pre-operative use of EGD, with systematic reviews revealing that only one-fifth of patients had EGD findings that influenced their operative management or delayed their surgery. The scope of EGD's utility in intraoperative and postoperative contexts remains underexplored. Direct evidence of EGD's clinical benefits in bariatric surgery is lacking, and its use is generally based on clinical judgment and individual patient considerations. Currently, a complete evidence chain is absent due to insufficient information regarding clinical validity.

Section Summary: Esophagogastroduodenoscopy with Bariatric Surgery

Current research has focused on pre-operative utility of EGD. The evidence evaluating the scope of EGD in both intraoperative and postoperative settings is lacking in comparison. Systematic reviews have found that only one-fifth of patients had findings from EGD that either altered their operative management or postponed their bariatric surgery. There is a need for direct, comparative, homogenous studies assessing whether EGD should be routine before bariatric surgery, and whether it is judicious to expose many patients to an invasive procedure that has potential risk and insufficient evidence of effectiveness.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Association of Clinical Endocrinologists and American College of Endocrinology

In 2016, the American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) jointly published comprehensive clinical guidelines on the medical care of individuals with obesity.[1,] The guidelines addressed 9 broad clinical questions with 123 recommendations. The recommendations specific to bariatric surgery are shown in Table 13. The guidelines noted that a de novo evidence-based review of questions pertaining to bariatric surgery was not undertaken. Instead, the 2013 guidelines from AACE, the Obesity Society, and the American

Society for Metabolic & Bariatric Surgery were reviewed and determined to be adequate. Key recommendations from those guidelines were included in the 2016 document and are shown in Table 9.

Table 9. Recommendations on Bariatric Surgery Included in the American Association of Clinical Endocrinologists and the American College of Endocrinology Guidelines for Medical Care of Patients with Obesity (2016)

Key Question	Recommendation	Evidence Grade	Best Evidence Level
9.1 Is bariatric surgery effective to treat obesity and weight-related complications?	R120. Patients with a BMI of ≥40 kg/m2 without coexisting medical problems and for whom the procedure would not be associated with excessive risk should be eligible for bariatric surgery	A	1
9.2 When should bariatric surgery be used to treat obesity and weight-related complications?	R121. Patients with a BMI of ≥35 kg/m^2 and 1 or more severe obesity-related complications, including T2D, hypertension, obstructive sleep apnea, obesity hypoventilation syndrome, Pickwickian syndrome, nonalcoholic fatty liver disease or nonalcoholic steatohepatitis, pseudotumor cerebri, gastroesophageal reflux disease, asthma, venous stasis disease, severe urinary incontinence, debilitating arthritis, or considerably impaired QOL may also be considered for a bariatric surgery procedure. Patients with BMI of 30 to 34.9 kg/m^2 with diabetes or metabolic syndrome may also be considered for a bariatric procedure, although current evidence is limited by the number of patients studied and lack of long-term data demonstrating net benefit.		
	BMI ≥35 kg/m^2 and therapeutic target of weight control and improved biochemical markers of CVD risk	A	1
	BMI ≥30 kg/m^2 and therapeutic target of weight control and improved biochemical markers of CVD risk	B	2
	BMI ≥30 kg/m^2 and therapeutic target of glycemic control in T2DM and improved biochemical markers of CVD risk	C	3
	R122. Independent of BMI criteria, there is insufficient evidence to recommend a bariatric surgical procedure specifically for glycemic control, lipid lowering, or CVD risk reduction alone	D	NA
	R123. All patients should undergo pre-operative evaluation for weight-related complications and causes of obesity, with special attention directed to factors that may affect a recommendation for bariatric surgery or be ameliorated by weight loss resulting from the procedure	A	1

BMI: body mass index; CVD: cardiovascular disease; NA: not applicable; QOL: quality of life; T2D: type 2 diabetes.

American Academy of Clinical Endocrinologists, ACE, the Obesity Society, the American Society for Metabolic and Bariatric Surgery, Obesity Medicine Association, and American Society of Anesthesiologists

In 2019, an update of the joint 2013 guidelines on support for bariatric surgery patients were published by the AACE, the Obesity Society, the American Society for Metabolic and Bariatric Surgery

(ASMBS), Obesity Medicine Association, and American Society of Anesthesiologists.[127,] Recommendations on the following questions are summarized below.

- "Which patients should be offered bariatric surgery?"
    - "Patients with a BMI [body mass index] ≥40 kg/m^2 without coexisting medical problems and for whom bariatric surgery would not be associated with excessive risk should be eligible for a bariatric procedure."
    - "Patients with a BMI ≥35 kg/m^2 and 1 or more severe obesity-related complications remediable by weight loss, including T2D, high risk for T2D, poorly controlled hypertension, nonalcoholic fatty liver disease/nonalcoholic steatohepatitis, OSA [obstructive sleep apnea], osteoarthritis of the knee or hip, and urinary stress incontinence, should be considered for a bariatric procedure."
    - "Patients with the following comorbidities and BMI≥35 kg/m^2 may also be considered for a bariatric procedure, though the strength of evidence is more variable; obesity-hypoventilation syndrome and Pickwickian syndrome after a careful evaluation of operative risk; idiopathic intracranial hypertension; [gastroesophageal reflux disease]; severe venous stasis disease; impaired mobility due to obesity, and considerably impaired quality of life."
    - "Patients with BMI of 30 to 34.9 kg/m^2 with T2D with inadequate glycemic control despite optimal lifestyle and medical therapy should be considered for a bariatric procedure; current evidence is insufficient to support recommending a bariatric procedure in the absence of obesity."
    - "The BMI criterion for bariatric procedures should be adjusted for ethnicity (e.g., 18.5 to 22.9 kg/m^2 is normal range, 23 to 24.9 kg/m^2 overweight, and ≥25 kg/m^2 obesity for Asians)." '(see Policy Guidelines)
    - "Bariatric procedures should be considered to achieve optimal outcomes regarding health and quality of life when the amount of weight loss needed to prevent or treat clinically significant obesity-related complications cannot be obtained using only structured lifestyle change with medical therapy."

- "Which bariatric surgical procedure should be offered?"
    - "Selecting a bariatric procedure should be based on individualized goals of therapy (e.g., weight loss target and/or improvement in specific obesity-related complications), available local-regional expertise (obesity specialists, bariatric surgeon, and institution), patient preferences, personalized risk stratification, and other nuances as they become apparent. Notwithstanding technical surgical reasons, laparoscopic bariatric procedures should be preferred over open bariatric procedures due to lower early postoperative morbidity and mortality. Laparoscopic adjustable gastric banding, sleeve gastrectomy, RYGB [Roux-en-y gastric bypass], and LBPD/DS [laproscopic biliopancreatic diversion/duodenal switch], or related procedures should be considered as primary bariatric and metabolic procedures performed in patients requiring weight loss and/or amelioration of obesity-related complications. Physicians must exercise caution when recommending BPD [biliopancreatic diversion], BPD with duodenal switch, or related procedures because of the greater associated nutritional risks related to the increased length of bypassed small intestine. Newer nonsurgical bariatric procedures may be considered for selected patients who are expected to benefit from short-term (i.e., about 6 months) intervention with ongoing and durable structured lifestyle with/without medical therapy."

American Society for Metabolic and Bariatric Surgery

In 2022, the ASMBS and the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) published a joint statement on the current available scientific information on metabolic and bariatric surgery and its indications.[128,] Since the NIH issued its statement on gastrointestinal surgery for severe obesity in 1991, there has been a significant expansion in the

understanding of obesity and metabolic and bariatric surgery (MBS).The authors note that a large body of clinical experience and research has emerged over the years, providing evidence of the safety, efficacy, and durability of MBS. Moreover, long-term studies have highlighted that MBS effectively treats clinically severe obesity and its associated co-morbidities, leading to a reduction in mortality rates when compared to non-operative treatment methods. Recommendations are summarized below.

- MBS is recommended for individuals with BMI ≥35 kg/ m^2, regardless of presence, absence, or severity of comorbidities.
- MBS is recommended in patients with T2D and BMI ≥30 kg/m^2.
- MBS should be considered in individuals with BMI of 30-34.9 kg/m^2 who do not achieve substantial or durable weight loss or co-morbidity improvement using nonsurgical methods.
- Obesity definitions using BMI thresholds do not apply similarly to all populations. Clinical obesity in the Asian population is recognized in individuals with BMI >25 kg/m^2 (see Policy Guidelines). Access to MBS should not be denied solely based on traditional BMI risk zones.
- There is no upper patient-age limit to MBS. Older individuals who could benefit from MBS should be considered for surgery after careful assessment of co-morbidities and frailty.
- Carefully selected individuals considered higher risk for general surgery may benefit from MBS.
- MBS is an effective treatment of clinically severe obesity in patients who need other specialty surgery, such as joint arthroplasty, abdominal wall hernia repair, or organ transplantation.
- Consultation with a multidisciplinary team can help manage the patient's modifiable risk factors with a goal of reducing risk of perioperative complications and improving outcomes. The ultimate decision for surgical readiness should be determined by the surgeon.
- Severe obesity is a chronic disease requiring long-term management after primary MBS. This may include revisional surgery or other adjuvant therapy to achieve desired treatment effect.

Individuals with Type 2 Diabetes Mellitus

In 2022, the AACE published updated guidelines for the comprehensive care of individuals with diabetes mellitus.[129,] Recommendations related to bariatric procedures are shown in Table 10.

Table 10. Recommendations on Bariatric Surgery Included in the American Association of Clinical Endocrinology Guidelines on Care of Persons with Diabetes Mellitus (2022)

Recommendation Number	Recommendation	Evidence Grade	Best Evidence Level
10.9	Persons with a BMI ≥35 kg/m^2 and 1 or more severe obesity-related complications remediable by weight loss, including T2D, high risk for T2D (insulin resistance, prediabetes, and/or metabolic syndrome), poorly controlled hypertension, NAFLD/NASH, OSA, osteoarthritis of the knee or hip, and urinary stress incontinence, should be considered for a bariatric procedure	C	3
10.10	Persons with BMI 30 to 34.9 kg/m^2 and T2D with inadequate glycemic control despite optimal lifestyle and medical therapy should be considered for a bariatric procedure	B	2

BEL: best evidence level; BMI: body mass index; GOE: grade of evidence; NAFLD: nonalcoholic fatty liver disease; NASH: nonalcoholic steatohepatitis; OSA: obstructive sleep apnea; T2D: type 2 diabetes.

Veterans Affairs/Department of Defense

In 2020, the Department of Veterans Affairs/Department of Defense (VA/DoD) published a clinical practice guideline for the management of adult overweight and obesity.[130,] Recommendations on bariatric surgery are shown in Table 11.

Table 11. Recommendations on Bariatric Surgery Included in VA/DoD Obesity Treatment Guidelines (2020)

Recommendation Number	Recommendation Statement	Strength of Evidence[1]
12	We suggest offering the option of metabolic/bariatric surgery, in conjunction with a comprehensive lifestyle intervention, to patients with a body mass index of ≥30 kg/m2 and type 2 diabetes mellitus.	Weak
13	We suggest offering the option of metabolic/bariatric surgery, in conjunction with a comprehensive lifestyle intervention, for long-term weight loss/maintenance and/or to improve obesity-associated condition(s) in adult patients with a body mass index ≥40 kg/m2 or those with body mass index ≥35 kg/m2 with obesity-associated condition(s).	Weak
14	There is insufficient evidence to recommend for or against metabolic/bariatric surgery to patients over age 65.	Neither for nor against
15	There is insufficient evidence to recommend for or against percutaneous gastrostomy devices for weight loss in patients with obesity.	Neither for nor against
16	We suggest offering intragastric balloons in conjunction with a comprehensive lifestyle intervention to patients with obesity (body mass index ≥30 kg/m^2) who prioritize short-term (up to six months) weight loss.	Weak
17	There is insufficient evidence to recommend for or against intragastric balloons for long-term weight loss to support chronic weight management or maintenance.	Neither for nor against

[1]The relative strength of the recommendation is based on a binary scale, "Strong" or "Weak." A strong recommendation indicates that the Work Group is highly confident that desirable outcomes outweigh undesirable outcomes. If the Work Group is less confident of the balance between desirable and undesirable outcomes, they present a weak recommendation.

Society of American Gastrointestinal and Endoscopic Surgeons

In 2013, the Society of American Gastrointestinal and Endoscopic Surgeons issued evidence-based guidelines on the management of a hiatal hernia, which included a recommendation about the repair of hiatal hernias incidentally detected at the time of bariatric surgery.[121,] These guidelines stated: "During operations for Roux-en-Y gastric bypass, sleeve gastrectomy and the placement of adjustable gastric bands, all detected hiatal hernias should be repaired" (moderate quality evidence, weak recommendation).

In 2024, the SAGES issues updated guidelines for the surgical treatment of hiatal hernias.[131,] Systematic reviews were conducted for four key questions regarding the treatment of HH in adults: surgical treatment of asymptomatic HH versus surveillance; use of mesh versus no mesh; performing a fundoplication versus no fundoplication; and RYGB versus redo fundoplication for recurrent HH. There was insufficient evidence to make evidence-based recommendations regarding surgical repair of asymptomatic HH or conversion to RYGB in recurrent HH, and therefore, only expert opinions were offered. The SAGES guidelines panel suggested that select asymptomatic patients may be offered surgical repair, with criteria outlined. Similarly, it suggested that conversion to RYGB for management of recurrent HH may be appropriate in certain patients and again described criteria. The evidence for the routine use of mesh in HH repair was equivocal and the panel deferred making a recommendation.

Guidelines for Children and Adolescents

Childerhose et al (2017) conducted a systematic review of adolescent bariatric surgery recommendation documents published in the United States and provided recommendations based on their review.[132,] The literature search was conducted from 1999 through 2013 and identified 16 recommendations for inclusion: 10 clinical practice guidelines, 4 position statements, and 2 consensus statements. Fifteen of the 16 publications recommended bariatric surgery for adolescents. The main reasons for recommending bariatric surgery for adolescents included: (1) surgery is effective in producing short- and long-term weight loss; (2) surgery is appropriate when the patient does not

respond to behavioral or medical interventions; (3) surgery is appropriate when serious comorbidities threaten the health of the patient; and (4) surgery can improve long-term health and/or emotional problems. Body mass index thresholds ranged from 35 kg/m^2 or more to 50 kg/m^2 or more, with lower thresholds usually requiring the presence of at least 1 serious comorbidity. The minimum age was specified in 10 publications, with most using physiologic maturity (Tanner stage IV and/or 95% of adult height based on bone age, corresponding to ≥13 years for females and to ≥15 years for males) rather than years.

American Academy of Pediatrics

In 2019, the American Academy of Pediatrics (AAP) published a report outlining the current evidence regarding adolescent bariatric surgery that provided recommendations for practitioners and policy makers.[133,] Within this report, AAP listed indications for adolescent metabolic and bariatric surgery that reflected 2018 ASMBS recommendations. Additionally, the AAP report noted that generally accepted contraindications to bariatric surgery included: "a medically correctable cause of obesity, untreated or poorly controlled substance abuse, concurrent or planned pregnancy, current eating disorder, or inability to adhere to postoperative recommendations and mandatory lifestyle changes." In 2023, the AAP published their first evidence-based clinical practice guideline for the evaluation and treatment of children and adolescents (ages 2 to 18 years) with obesity.[134,] The recommendations put forth in the guideline are based on evidence from RCTs and comparative effectiveness trials, along with high-quality longitudinal and epidemiologic studies gathered in a systematic review process described in their methodology. The AAP's recommendation related to bariatric surgery is below:

- "Pediatricians and other PHCPs [pediatric health care providers] should offer referral for adolescents 13 years and older with severe obesity (BMI ≥ 120% of the 95th percentile for age and sex) for evaluation for metabolic and bariatric surgery to local or regional comprehensive multidisciplinary pediatric metabolic and bariatric surgery centers (Grade C Evidence Quality)."

They list indications for adolescent metabolic and bariatric surgery (Table 12) that align with the 2019 indications.

Table 12. Indications for Adolescent Metabolic and Bariatric Surgery

Weight Criteria	Comorbid Conditions
Class 2 obesity; BMI ≥35, or 120% of the 95th percentile for age and sex, whichever is lower **Class 3 obesity; BMI ≥40, or 140% of the 95th percentile for age and sex, whichever is lower**	Clinically significant disease, including, but not limited to, OSA (AHI >5), T2D, IIH, NASH, Blount disease, SCFE, depressed health-related quality of life, and hypertension Not required but commonly present

AHI: apnea-hypopnea index; BMI: body mass index; IIH: idiopathic intracranial hypertension; NASH: non-alcoholic steatohepatitis; OSA: obstructive sleep apnea; SCFE: slipped capital femoral epiphysis; T2D: type 2 diabetes.

American Society for Metabolic and Bariatric Surgery

In 2012, the ASMBS best practice guidelines found that current evidence was insufficient to discriminate among specific bariatric procedures, but allowed that there was an increasing body of data showing safety and efficacy of Roux-en-Y gastric bypass and adjustable gastric band for the pediatric population.[135,] Bariatric surgery was recommended for pediatric patients with morbid obesity and the following comorbidities:

- Strong indications: T2D, moderate or severe obstructive sleep apnea (apnea-hypopnea index >15), nonalcoholic steatohepatitis, pseudotumor cerebri.
- Less strong indications: cardiovascular disease, metabolic syndrome.

The guidelines stated that depression and eating disorders should not be considered exclusion criteria for bariatric surgery. The guidelines also noted that depression should be monitored following

the procedure and that eating disorders should be treated and the patient stabilized before the procedure.

In 2018, ASBMS published an update to the 2012 guideline.[136,] Summary of major changes in the guideline included:

- "Vertical sleeve gastrectomy has become the most used and most recommended operation in adolescents with severe obesity for several reasons, near-equivalent weight loss to RYGB in adolescents, fewer reoperations, better iron absorption, and near-equivalent effect on comorbidities as RYGB in adolescents. However, given the more extensive long-term data available for RYGB, we can recommend the use of either RYGB or VSG in adolescents. Long-term outcomes of after vertical sleeve gastrectomy are still not well understood."
- "There are no data that the number of preoperative weight loss attempts correlated with success after metabolic/bariatric surgery. Compliance with a multidisciplinary preoperative program may improve outcomes after metabolic/bariatric surgery but prior attempts at weight loss should be removed as a barrier to definitive treatment for obesity."
- "The use of the most up to date definitions of childhood obesity are as follows: (1) BMI cut offs of 35 kg/m^2 or 120% of the 95th percentile with a comorbidity, or (2) BMI >40 kg/m^2 or 140% of the 95th percentile without a comorbidity (whichever is less). Requiring adolescents with a BMI >40 to have a comorbidity (as in the old guidelines) puts children at a significant disadvantage to attaining a healthy weight. Earlier surgical intervention (at a BMI <45 kg/$m^{2)}$ can allow adolescents to reach a normal weight and avoid lifelong medication therapy and end organ damage from comorbidities."
- "Certain comorbidities should be considered in adolescents, specifically the psychosocial burden of obesity, the orthopedic diseases specific to children, , and cardiac risk factors. Given the poor outcomes of medical therapies for T2D in children, these comorbidities may be considered an indication for metabolic/bariatric surgery in younger adolescents or those with lower obesity percentiles."
- "Vitamin B deficiencies, especially B1 appear to be more common in adolescents both preoperatively and postoperatively; they should be screened for and treated. Prophylactic B1 for the first 6 months postoperatively is recommended as is education of patients and primary care providers on the signs and symptoms of common deficiencies."
- "Developmental delay, autism spectrum, or syndromic obesity should not be a contraindication to metabolic/bariatric surgery. Each patient and caregiver team will need to be assessed for the ability to make dietary and lifestyle changes required for surgery. Multidisciplinary teams should agree on the specific needs and abilities of the given patient and caregiver and these should be considered on a case-by-case basis with the assistance of the hospital ethics committee where appropriate."
- "Because metabolic/bariatric surgery results in better weight loss and resolution of comorbidities in adolescents at lower BMI's with fewer comorbidities, referrals should occur early, as soon as a child is recognized to suffer from severe obesity disease (BMI >120% of the 95th percentile or BMI of 35). Prior weight loss attempts, Tanner stage, and bone age should not be considered when referring patients to a metabolic/bariatric surgery program."
- "Unstable family environments, eating disorders, mental illness, or prior trauma should not be considered contraindications for metabolic/bariatric surgery in adolescents; however, these should be optimized and treated where possible before and surrounding any surgical intervention for obesity."

In 2022, the ASMBS updated their guideline on indications for metabolic and bariatric surgery.[128,] They noted that prospective data demonstrated durable weight loss and maintained co-morbidity remission in patients as young as 5 years of age. Additionally, the ASMBS stated that metabolic and bariatric surgery do not negatively impact pubertal development or linear growth, and therefore a specific Tanner stage and bone age should not be considered a requirement for surgery. Other statements supported 2018 recommendations, including that syndromic obesity, developmental

delay, autism spectrum, or a history of trauma would not be considered a contraindication to bariatric surgery in children or adolescents. The ASMBS's recommendation related to bariatric surgery in adolescents is below:

- "Children and adolescents with BMI. >120% of the 95th percentile and a major co-morbidity, or a BMI >140% of the 95th percentile, should be considered for MBS after evaluation by a multidisciplinary team in a specialty center."

Endocrine Society

In 2008, the Endocrine Society published recommendations on the prevention and treatment of pediatric obesity.[137,] In 2017, the Society sponsored an update of these guidelines by the Pediatric Endocrine Society and the European Society of Endocrinology.[138,] These guidelines recommended the following:

"We suggest that bariatric surgery be considered only under the following conditions:

- The child has attained Tanner 4 or 5 pubertal development and final or near-final adult height.
- The child has a BMI > 40 kg/m^2 or has BMI above 35 kg/m^2 and significant, extreme comorbidities.
- Extreme obesity and comorbidities persist, despite compliance with a formal program of lifestyle modification, with or without a trial of pharmacotherapy.
- Psychological evaluation confirms the stability and competence of the family unit.
- There is access to an experienced surgeon in a pediatric bariatric surgery center of excellence that provides the necessary infrastructure for patient care, including a team capable of long-term follow-up of the metabolic and psychosocial needs of the patient and family.
- The patient demonstrates the ability to adhere to the principles of healthy dietary and activity habits.

We recommend against bariatric surgery for preadolescent children, for pregnant or breast-feeding adolescents (and those planning to become pregnant within 2 yr of surgery) and in any patient who has not mastered the principles of healthy dietary and activity habits and/or has an unresolved substance abuse, eating disorder, or untreated psychiatric disorder."

Guidelines for Esophagogastroduodenoscopy

American Society for Metabolic and Bariatric Surgery

In 2021, the ASMBS issued a position statement addressing the need and strategies for preoperative endoscopic screening and postoperative surveillance for mucosal abnormalities in patients undergoing bariatric surgery, specifically for patients undergoing SG and RYGB.[126,] The statement, based on current clinical knowledge and expert opinion, also notes that the general principles may apply to other procedures like BPD and BPD with DS, though there is paucity of procedure-specific literature. The ASMBS emphasizes that this statement does not establish a standard of care and will be updated as new evidence emerges. The ASMBS provided the following summary:

Table 13. Summary of ASMBS Recommendations for Upper Gastrointestinal Endoscopy

Upper Gastrointestinal Endoscopy Before Bariatric Surgery	Upper Gastrointestinal Endoscopy After Bariatric Surgery
Clinical evaluation by symptoms alone does not reliably diagnose or rule out GERD, and upper gastrointestinal abnormalities are found in a significant proportion of patients undergoing EGD before bariatric surgery, even in asymptomatic patients. While some of these findings do not modify medical or surgical management, routine preoperative EGD is justifiable and should be done at the surgeon's discretion.	After bariatric surgery, screening with EGD should be considered for all patients with gastrointestinal symptoms, including GERD symptoms. It is reasonable to perform EGD on patients ≥3 years after SG, irrespective of GERD symptoms, to rule out Barrett's esophagus. More long-term surveillance every 5 years after that would be reasonable even if the index screening EGD is normal and is compatible with clinicians exercising an abundance of caution until better-designed and longer term studies are available.

EGD: Esophagogastroduodenoscopy; GERD: gastroesophageal reflux disease; SG: sleeve gastrectomy.

American Gastroenterological Association

In 2024, the American Gastroenterological Association published a practice update on performing high-quality upper endoscopy.[139,] The best practice statements include confirming an appropriate indication for EGD, ensuring adequate visualization with mucosal cleansing and insufflation, and using a high-definition white-light endoscopy system. The guidance also endorses careful gastric mucosal inspection in anterograde and retroflexed views and documenting abnormalities using established classifications and standard terminology, whenever possible.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

In 2006, the Centers for Medicare & Medicaid Services published a National Coverage Determination on bariatric surgery.[140,] The Centers determined that:
"...the evidence is adequate to conclude that open and laparoscopic Roux-en-Y gastric bypass (RYGBP), laparoscopic adjustable gastric banding (LAGB), and open and laparoscopic biliopancreatic diversion with duodenal switch (BPD/DS), are reasonable and necessary for Medicare beneficiaries who have a body mass index (BMI) ≥35, have at least 1 co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity."

The decision memo also states, "The evidence is not adequate to conclude that the following bariatric surgery procedures are reasonable and necessary; therefore, the following are non-covered for all Medicare beneficiaries:

1. open vertical banded gastroplasty;
2. laparoscopic vertical banded gastroplasty;
3. open sleeve gastrectomy;
4. laparoscopic sleeve gastrectomy; and
5. open adjustable gastric banding."[140,]

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 14.

Table 14. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT06200961	Use of Sedation-Free Transnasal Endoscopy to Improve Access and Lower Costs of Endoscopic Evaluations in a Bariatric Medical and Surgical Program	100	Dec 2025
NCT02390973[a]	Surgery Versus Best Medical Management for the Long Term Remission of Type 2 Diabetes and Related Diseases (REMISSION)	408	Mar 2029
NCT02328599	A Prospective Consortium Evaluating the Long-term Follow-up of Patients With Type 2 Diabetes Enrolled In a Randomized Controlled Trial Comparing Bariatric Surgery Versus Medical Management (ARMMS-T2D)	302	Jun 2031
NCT03610256	Prospective Multicentric Randomized Trial Comparing the Efficacy and Safety of single anastomosis- Duodeno Ileal Bypass With Sleeve Gastrectomy (SADI-S) Versus Roux-en-Y Gastric Bypass (RYGB) (SADISLEEVE)	382	Dec 2031
NCT03517072	Determinants of the Long-Term Success of Bariatric Surgery	1000	Jan 2024
NCT03472157	Prospective Multicentric, Open Label, Randomized Clinical Trial of Superiority, With Two Arms, Comparing Bariatric Surgery to the Recommended Medical Treatment for NASH (NASHSURG)	100	Mar 2026

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT04506190	A Prospective Multicenter Study to Evaluate the Perioperative Outcomes of Laparoscopic and Robotic-Assisted Revisional Bariatric Surgery	100	Sep 2024
NCT04128995	Surgical or Medical Treatment for Pediatric Type 2 Diabetes	100	Dec 2025
NCT03236142	The Single, 300 cm Loop, Duodenal Switch (SIPS) Results in Less Nutritional Deficiencies Than the Standard Duodenal Switch (DS) Operation: A Multicenter, Randomized Controlled Trial	110	Jan 2025
NCT02692469	Laparoscopic single anastomosis- Duodenal-Jejunal Bypass With Sleeve Gastrectomy vs Laparoscopic Duodenal Switch as a Primary Bariatric Procedure. 5 Year Patient Follow	140	Apr 2026
NCT04165694	Single Anastomosis Duodenal Ileal Bypass (SADI) as a Second Stage for Sleeve Gastrectomy Weight Loss Failure	54	Dec 2030
NCT01172899	The BASIC Trial. Morbid Obesity in Children and Adolescents: a Prospective Randomised Trial of Conservative Treatment Versus Surgery	60	Dec 2022 (unknown status)

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

Appendix 1

Table A1. Comparison of Studies Included in Systematic Reviews & Meta-analyses

Study	Gloy et al (2013)[141,]	Puzziferri et al (2014)[142,]	Colquitt et al (2014)[143,]	Kang et al (2017)[144,]	Park et al (2019)[145,]	Cosentino et al (2021)[146,]
Hall et al (1990)		●				
Pories et al (1995)		●				
Heindorff et al (1997)	●					
Mingrone et al (2002)	●					●
Lee et al (2004)						●
Langer et al (2005)					●	
Lee et al (2005)					●	
Olbers et al (2005)					●	
van Dielen et al (2005)		●			●	
O'Brien et al (2005)		●				
Ponce et al (2005)		●				
Suter et al (2005)		●				
Olbers et al (2006)						●
Himpens et al (2006)			●	●		●
O'Brien et al (2006)	●		●		●	●
Skroubis et al (2006)		●			●	●
van Mastrigt et al (2006)					●	
Kalfarentzos et al (2006)		●				
Basdevant et al (2007)		●				
Czupryniak et al (2007)		●				
Favretti et al (2007)		●				
Gravante et al (2007)		●				

Study	Gloy et al (2013)[141],	Puzziferri et al (2014)[142],	Colquitt et al (2014)[143],	Kang et al (2017)[144],	Park et al (2019)[145],	Cosentino et al (2021)[146],
Mathus-Vliegen et al (2007)		●				
Angrisani et al (2007)			●	●		
Sekhar et al (2007)		●				
Weiner et al (2007)		●				
Dixon et al (2008)	●		●		●	●
Karamanakos et al (2008)			●	●	●	●
Vagenas et al (2008)		●				
Yan et al (2008)		●				
Aasheim et al (2009)			●			
Angrisani et al (2009)					●	
Phillips et al (2009)		●				
Scozzari et al (2009)					●	●
Nguyen et al (2009)		●	●	●	●	●
Caiazzo et al (2010)		●				
Hauser et al (2010)		●				
Nogues et al (2010)			●			
O'Brien et al (2010)	●				●	
Reis et al (2010)	●					
Sovik et al (2010)					●	
Sultan et al (2010)		●				
Kehagias et al (2011)				●	●	●
Lee et al (2011)			●		●	
Ray and Ray (2011)		●				
Sovik et al (2011)		●				●
Van Nieuwenhove et al (2011)		●				
Adams et al (2012)		●				
Dixon et al (2012)	●					●
Hedberg et al (2012)			●			
Paluszkiewicz et al (2012)			●	●	●	
Praveen et al (2012)			●		●	
Peterli et al (2012)			●			
Mingrone et al (2012)	●	●		●	●	
Ramon et al (2012)				●		●
Schauer et al (2012)	●		●		●	
Courcoulas et al (2013)		●				
Darabi et al (2013)					●	●
Demerdash et al (2013)			●			
Kehagias et al (2013)		●				
Keidar et al (2013)			●	●		●
Liang et al (2013)	●		●			

Study	Gloy et al (2013)[141],	Puzziferri et al (2014)[142],	Colquitt et al (2014)[143],	Kang et al (2017)[144],	Park et al (2019)[145],	Cosentino et al (2021)[146],
Ikramuddin et al (2013)	●		●			
Peterli et al (2013)				●		
Sharma et al (2013)			●			
Vix et al (2013)			●	●		
MacLaughlin et al (2014)						●
Parikh et al (2014)						●
Gras-Miralles et al (2014)					●	
Courcoulas et al (2014)					●	
Schauer et al (2014)					●	
Vix et al (2014)						●
Zhang et al (2014)				●	●	
Courcoulas et al (2015)						●
Feigel-Guiller et al (2015)					●	
Mingrone et al (2015)					●	●
Risstad et al (2015)						●
Yang et al (2015)					●	
Cummings et al (2016)					●	●
Grubnik et al (2016)					●	●
Ikramuddin et al (2016)					●	
Pilone et al (2016)					●	
Tang et al (2016)					●	
Biter et al (2017)					●	●
Casajoana et al (2017)					●	●
Ignat et al (2017)					●	●
Kalinowski et al (2017)						●
Murphy et al (2017)						●
Peterli et al (2017)					●	
Schauer et al (2017)					●	
Risstad et al (2017)					●	
Seetharamaiah et al (2017)					●	●
Sullivan et al (2017)						●
Miller et al (2017)						●
Capristo et al (2018)						●
Ikramuddin et al (2018)					●	●
Murphy et al (2018)					●	
Talebpour et al (2018)					●	●
Peterli et al (2018)					●	●
Salminen et al (2018)					●	●
Schiavon et al (2018)						●

Study	Gloy et al (2013)[141]	Puzziferri et al (2014)[142]	Colquitt et al (2014)[143]	Kang et al (2017)[144]	Park et al (2019)[145]	Cosentino et al (2021)[146]
Shivakumar et al (2018)						●
Simonson et al (2018)						●
Robert et al (2019)						●

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Documentation for Clinical Review

Please provide the following documentation:
Initial Bariatric Procedure or Revision for Inadequate Weight Loss

- History and physical and/or consultation notes including prior weight loss attempts and responses, and comorbidities (if needed):
  - Documentation of failed weight loss by conservative measures in adults (ages 18 and older) in adults with Class 3 Obesity with body mass index (BMI) greater than or equal to 40.0 kg/m^2)
    OR
  - Diagnosis of at least 1 obesity-related comorbid condition with BMI greater than or equal to 35 to 39.9 kg/m^2 in adults with Class 2 Obesity
    OR
  - Diagnosis of type 2 diabetes in individuals with Class 1 obesity with BMI greater than or equal to30 to 34.9 kg/m^2

Revision Bariatric Surgery:

- Documentation of the problem needing correction (history and physical and/or consultation notes including: prior surgery and complications as applicable, indication for surgery, and treatment plan), which may include, but are not limited to:
  - Staple-line failure or leakage
  - Obstruction, stricture, erosion, or fistula
  - Gastroesophageal reflux disease (GERD), based on ambulatory pH probe monitoring, or endoscopic findings of ulcer, strictures, Barrett's esophagus, or esophagitis and failing maximal medical therapy
  - Pouch enlargement documented by endoscopy and prior successful weight loss
  - Nonabsorption resulting in hypoglycemia or malnutrition
  - Weight loss of 20% or more below ideal body weight
  - Band slippage or herniation that cannot be corrected with manipulation or adjustment

Bariatric Surgery in Adolescents:

- Documentation requested for Initial Bariatric Procedure in Adults with Obesity

- Documentation of psychological counseling
- Documentation of informed consent
- Documentation that any device used for bariatric surgery is in accordance with the FDA-approved indication for use

Concomitant Hiatal Hernia Repair:

- Documentation of preoperatively-diagnosed hiatal hernia with indications for surgical repair

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	0813T	Esophagogastroduodenoscopy, flexible, transoral, with volume adjustment of intragastric bariatric balloon
	43290	Esophagogastroduodenoscopy, flexible, transoral; with deployment of intragastric bariatric balloon
	43291	Esophagogastroduodenoscopy, flexible, transoral; with removal of intragastric bariatric balloon(s)
	43332	Repair, paraesophageal hiatal hernia (including fundoplication), via laparotomy, except neonatal; without implantation of mesh or other prosthesis
	43333	Repair, paraesophageal hiatal hernia (including fundoplication), via laparotomy, except neonatal; with implantation of mesh or other prosthesis
	43334	Repair, paraesophageal hiatal hernia (including fundoplication), via thoracotomy, except neonatal; without implantation of mesh or other prosthesis
	43335	Repair, paraesophageal hiatal hernia (including fundoplication), via thoracotomy, except neonatal; with implantation of mesh or other prosthesis
	43336	Repair, paraesophageal hiatal hernia, (including fundoplication), via thoracoabdominal incision, except neonatal; without implantation of mesh or other prosthesis
	43337	Repair, paraesophageal hiatal hernia, (including fundoplication), via thoracoabdominal incision, except neonatal; with implantation of mesh or other prosthesis
	43632	Gastrectomy, partial, distal; with gastrojejunostomy
	43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)
	43645	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption
	43659	Unlisted laparoscopy procedure, stomach

Type	Code	Description
	43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (e.g., gastric band and subcutaneous port components)
	43771	Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only
	43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only
	43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only
	43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components
	43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (i.e., sleeve gastrectomy)
	43842	Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty
	43843	Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty
	43845	Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)
	43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy
	43847	Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption
	43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)
	43860	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; without vagotomy
	43865	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; with vagotomy
	43886	Gastric restrictive procedure, open; revision of subcutaneous port component only
	43887	Gastric restrictive procedure, open; removal of subcutaneous port component only
	43888	Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only
	43999	Unlisted procedure, stomach
HCPCS	C9784	Gastric restrictive procedure, endoscopic sleeve gastroplasty, with esophagogastroduodenoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components
	C9785	Endoscopic outlet reduction, gastric pouch application, with endoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
04/14/1970	New Policy Adoption
02/26/1997	Policy Review
11/10/1999	Administrative Review External Review of policy
04/17/2000	Administrative Review Deleted Metropolitan Tables
01/22/2001	Administrative Review Morbid Obesity definition
02/13/2002	BCBSA Medical Policy adoption Open and Laparoscopic adjustable silicone gastric banding
04/17/2002	Administrative Review Distal Gastric Bypass with Duodenal Switch clarification
08/01/2002	Coding Update
09/01/2003	Policy Revision Updated
12/01/2003	Policy Revision Updated
02/01/2004	Policy Revision Updated Duodenal Switch
06/01/2004	Policy Revision Coding update Laparoscopic Gastric Banding CTAF update
01/01/2005	Policy Revision Coding update
09/01/2005	Policy Revision External review and recommendations for revision to policy statement: Duodenal Switch
12/01/2005	Policy Statement Revision
03/01/2006	Policy Revision Policy Statement Revision for Duodenal Switch and Lap Gastric Bypass Coding update
06/01/2006	Policy Name Change
12/07/2006	BCBSA Medical Policy adoption
03/12/2007	Policy Review CTAF review
03/24/2008	Coding Update
07/08/2008	Policy Revision Added lap banding adjustment, rationale, references Coding update
09/25/2009	Policy Title Revision Criteria revised
02/05/2010	Policy revision with position change Coding update
08/06/2010	Policy revision with position change
09/13/2010	Documentation required for clinical review update
11/04/2010	Policy revision for clarification of criteria
11/12/2010	Policy revision for clarification of criteria
04/01/2011	Policy revision for clarification of criteria
06/28/2013	Coding update
04/30/2015	Policy revision with position change effective 6/30/2015
06/30/2015	Policy revision with position change
07/31/2015	Policy clarification update
06/01/2016	Policy revision without position change

Effective Date	Action
05/01/2017	Policy revision without position change
12/01/2017	Policy revision without position change
04/01/2018	Policy revision without position change
11/01/2018	Policy statement clarification
04/01/2019	Policy revision without position change
05/01/2020	Annual Review. Policy statement, guidelines and literature updated.
04/01/2021	Annual Review. No change to policy statement. Policy guidelines and literature updated.
02/01/2022	Coding update.
05/01/2022	Annual review. No change to policy statement. Literature review updated.
01/01/2023	Annual review. Policy statement and guidelines updated.
02/01/2023	Policy statement updated. Coding update.
05/01/2023	Policy statement, guidelines and literature updated.
08/01/2023	Policy statement and guidelines updated. Coding update.
10/01/2023	Policy statement updated.
11/01/2024	Annual review. Policy statement, guidelines and literature updated.
02/01/2025	Annual review. Policy statement, guidelines and literature review updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE Red font: Verbiage removed	**AFTER** Blue font: Verbiage Changes/Additions
Bariatric Surgery 7.01.47 **Policy Statement:** **Bariatric Surgery in Adults With Class 3 Obesity (BMI greater than or equal to 40 kg/m^2)** I. The following bariatric surgery procedures may be considered **medically necessary** for the treatment of class 3 obesity (BMI greater than or equal to 40.0 kg/m^2) in adults (ages 18 and older) who have failed weight loss by conservative measures: A. Open or laparoscopic gastric bypass using a Roux-en-Y B. Laparoscopic adjustable gastric banding C. Open or laparoscopic sleeve gastrectomy (SG) D. Open or laparoscopic biliopancreatic bypass/diversion (i.e., Scopinaro procedure) with duodenal switch (DS) **Bariatric Surgery in Adults With Class 2 Obesity (BMI greater than or equal to 35 to 39.9 kg/m^2)** II. The following bariatric surgery procedures may be considered **medically necessary** for the treatment of class 2 obesity in individuals with at least 1 obesity-related comorbid condition (see Policy Guidelines) who have failed weight loss by conservative measures: A. Open or laparoscopic gastric bypass using a Roux-en-Y B. Laparoscopic adjustable gastric banding C. Open or laparoscopic sleeve gastrectomy (SG) D. Open or laparoscopic biliopancreatic bypass/diversion (i.e., Scopinaro procedure) with duodenal switch (DS) Bariatric surgery should be performed in appropriately selected individuals, by surgeons who are adequately trained and experienced in the specific techniques used, and in institutions that support a comprehensive bariatric surgery program, including long-term monitoring and follow-up postsurgery. (see Policy Guidelines for bariatric surgery selection criteria).	**Bariatric Surgery 7.01.47** **Policy Statement:** **Bariatric Surgery in Adults With Class 3 Obesity (BMI greater than or equal to 40 kg/m^2)** I. The following bariatric surgery procedures may be considered **medically necessary** for the treatment of class 3 obesity (BMI greater than or equal to 40.0 kg/m^2) in adults (ages 18 and older) who have failed weight loss by conservative measures: A. Open or laparoscopic gastric bypass using a Roux-en-Y B. Laparoscopic adjustable gastric banding C. Open or laparoscopic sleeve gastrectomy (SG) D. Open or laparoscopic biliopancreatic bypass/diversion (i.e., Scopinaro procedure) with duodenal switch (DS) **Bariatric Surgery in Adults With Class 2 Obesity (BMI greater than or equal to 35 to 39.9 kg/m^2)** II. The following bariatric surgery procedures may be considered **medically necessary** for the treatment of class 2 obesity in individuals with at least 1 obesity-related comorbid condition who have failed weight loss by conservative measures: A. Open or laparoscopic gastric bypass using a Roux-en-Y B. Laparoscopic adjustable gastric banding C. Open or laparoscopic sleeve gastrectomy (SG) D. Open or laparoscopic biliopancreatic bypass/diversion (i.e., Scopinaro procedure) with duodenal switch (DS) Bariatric surgery should be performed in appropriately selected individuals, by surgeons who are adequately trained and experienced in the specific techniques used, and in institutions that support a comprehensive bariatric surgery program, including long-term monitoring and follow-up postsurgery.

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Bariatric Surgery in Individuals With Class 1 Obesity (BMI greater than or equal to 30 to 34.9 kg/m^2) and Type 2 Diabetes III. For individuals with Class 1 obesity (BMI greater than or equal to 30 to 34.9 kg/m^2) and type 2 diabetes, the following bariatric surgery procedures may be considered **medically necessary** in adults who have failed weight loss by conservative measures: A. Open or laparoscopic gastric bypass using a Roux-en-Y B. Laparoscopic adjustable gastric banding C. Open or laparoscopic sleeve gastrectomy (SG) D. Open or laparoscopic biliopancreatic bypass/diversion (i.e., Scopinaro procedure) with duodenal switch (DS) IV. Bariatric surgery is considered **investigational** for individuals with Class 1 obesity who do not have type 2 diabetes. V. Bariatric surgery is considered **investigational** for individuals with a BMI less than 30 kg/m^2. VI. The following bariatric surgery procedures are considered **investigational** for the treatment of obesity: A. Vertical-banded gastroplasty B. Gastric bypass using a Billroth II type of (mini-gastric bypass) C. Biliopancreatic diversion (BPD) without DS D. Long-limb gastric bypass procedure (i.e., greater than 150 cm) E. Two-stage bariatric surgery procedures (e.g., SG as initial procedure followed by BPD at a later time) F. Laparoscopic gastric plication G. Single anastomosis duodeno-ileal bypass with SG **Revision Bariatric Surgery** VII. Revision surgery to address perioperative or late complications of a bariatric procedure may be considered **medically necessary**. These include but are not limited to: A. Staple line failure B. Obstruction C. Stricture	**Bariatric Surgery in Individuals With Class 1 Obesity (BMI greater than or equal to 30 to 34.9 kg/m^2) and Type 2 Diabetes** III. For individuals with Class 1 obesity (BMI greater than or equal to 30 to 34.9 kg/m^2) and type 2 diabetes, the following bariatric surgery procedures may be considered **medically necessary** in adults who have failed weight loss by conservative measures: A. Open or laparoscopic gastric bypass using a Roux-en-Y B. Laparoscopic adjustable gastric banding C. Open or laparoscopic sleeve gastrectomy (SG) D. Open or laparoscopic biliopancreatic bypass/diversion (i.e., Scopinaro procedure) with duodenal switch (DS) IV. Bariatric surgery is considered **investigational** for individuals with Class 1 obesity who do not have type 2 diabetes. V. Bariatric surgery is considered **investigational** for individuals with a BMI less than 30 kg/m^2. VI. The following bariatric surgery procedures are considered **investigational** for the treatment of obesity: A. Vertical-banded gastroplasty B. Gastric bypass using a Billroth II type of (mini-gastric bypass) C. Biliopancreatic diversion (BPD) without DS D. Long-limb gastric bypass procedure (i.e., greater than 150 cm) E. Two-stage bariatric surgery procedures (e.g., SG as initial procedure followed by BPD at a later time) F. Laparoscopic gastric plication G. Single anastomosis duodeno-ileal bypass with SG **Revision Bariatric Surgery** VII. Revision surgery to address perioperative or late complications of a bariatric procedure may be considered **medically necessary**. These include but are not limited to: A. Staple line failure B. Obstruction C. Stricture

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D. Nonabsorption resulting in hypoglycemia or malnutrition E. Weight loss of 20% or more below ideal body weight F. Band slippage that cannot be corrected with manipulation or adjustment (see policy guidelines section)	D. Nonabsorption resulting in hypoglycemia or malnutrition E. Weight loss of 20% or more below ideal body weight F. Band slippage that cannot be corrected with manipulation or adjustment (see policy guidelines section)
VIII. Revision of a primary bariatric procedure that has failed due to dilation of the gastric pouch or dilation proximal to an adjustable gastric band (documented by upper gastrointestinal examination or endoscopy) may be considered **medically necessary** if the initial procedure was successful in inducing weight loss prior to pouch dilation, and the individual has been compliant with a prescribed nutrition and exercise program.	VIII. Revision of a primary bariatric procedure that has failed due to dilation of the gastric pouch or dilation proximal to an adjustable gastric band (documented by upper gastrointestinal examination or endoscopy) may be considered **medically necessary** if the initial procedure was successful in inducing weight loss prior to pouch dilation, and the individual has been compliant with a prescribed nutrition and exercise program.
IX. Revision surgery to address severe gastroesophageal reflux disease refractory to medical treatment may be considered **medically necessary**.	IX. Revision surgery to address severe gastroesophageal reflux disease refractory to medical treatment may be considered **medically necessary**.
Bariatric Surgery in Adolescents X. Bariatric surgery in adolescents may be considered **medically necessary** according to similar weight-based criteria used for adults, but greater consideration should be given to psychosocial and informed consent issues (see Policy Guidelines section). In addition, any devices used for bariatric surgery must be used in accordance with the U.S. Food and Drug Administration approved indications.	**Bariatric Surgery in Adolescents** X. Bariatric surgery in adolescents may be considered **medically necessary** according to similar weight-based criteria used for adults, but greater consideration should be given to psychosocial and informed consent issues. In addition, any devices used for bariatric surgery must be used in accordance with the U.S. Food and Drug Administration approved indications.
Bariatric Surgery in Preadolescent Children XI. Bariatric surgery is considered **investigational** for the treatment of obesity in preadolescent children.	**Bariatric Surgery in Preadolescent Children** XI. Bariatric surgery is considered **investigational** for the treatment of obesity in preadolescent children.
Concomitant Hiatal Hernia Repair With Bariatric Surgery XII. Repair of a hiatal hernia at the time of bariatric surgery may be considered **medically necessary** for individuals who have a preoperatively diagnosed hiatal hernia with indications for surgical repair (see Policy Guidelines section).	**Concomitant Hiatal Hernia Repair With Bariatric Surgery** XII. Repair of a hiatal hernia at the time of bariatric surgery may be considered **medically necessary** for individuals who have a preoperatively diagnosed hiatal hernia with indications for surgical repair.

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XIII. Repair of a hiatal hernia that is diagnosed at the time of bariatric surgery, or repair of a preoperatively diagnosed hiatal hernia in individuals who do not have indications for surgical repair is considered **investigational**. **Endoscopic Procedures** XIV. The following endoscopic procedures are **investigational** as a primary bariatric procedure or as a revision procedure (i.e., to treat weight gain after bariatric surgery to remedy large gastric stoma or large gastric pouches): A. Insertion of the StomaphyX™ device, B. Endoscopic gastroplasty, C. Use of an endoscopically placed duodenojejunal sleeve, D. Intragastric balloons, and E. Aspiration therapy device.	XIII. Repair of a hiatal hernia that is diagnosed at the time of bariatric surgery, or repair of a preoperatively diagnosed hiatal hernia in individuals who do not have indications for surgical repair is considered **investigational**. **Endoscopic Procedures** XIV. The following endoscopic procedures are **investigational** as a primary bariatric procedure or as a revision procedure (i.e., to treat weight gain after bariatric surgery to remedy large gastric stoma or large gastric pouches): A. Insertion of the StomaphyX™ device, B. Endoscopic gastroplasty, C. Use of an endoscopically placed duodenojejunal sleeve, D. Intragastric balloons, and E. Aspiration therapy device. **Esophagogastroduodenoscopy with Bariatric Surgery** XV. The routine use of esophagogastroduodenoscopy with bariatric surgery is considered investigational.